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Radiation Protection in Mammography

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Radiation Protection in Mammography

Recommended Safety Procedures for the Use of Mammographic X-Ray Equipment

Safety Code 33

Environmental Health Directorate
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Explanatory notes

This document is one of a series of safety codes prepared by the Radiation Protection Bureau of Health Canada to set out requirements for the safe use of radiation-emitting equipment.

This Safety Code has been prepared to provide specific guidance to the radiologist, radiology technologist, medical physicist, radiation safety officer, and other personnel concerned with safety procedures and equipment performance in mammography.

For mammographic X-ray facilities, this code supersedes parts of Safety Code 20A, entitled "X-ray Equipment in Medical Diagnosis Part a: Recommended Safety Procedures for installation and use". This Safety Code is intended to complement X-ray equipment design, construction and performance standards promulgated under the Radiation Emitting Devices Act.

The safety procedures, equipment and installation guidelines detailed in this Safety Code are primarily for the instruction and guidance of persons employed in Federal Public Service departments and agencies, as well as those under the jurisdiction of the Canada Labour Code. Facilities under provincial jurisdiction may be subject to requirements specified under provincial statutes. The authorities listed in Appendix IV should be contacted for details of the regulatory requirements of individual provinces.

Certain words in this code have been chosen with purpose. The words *must* and *shall* indicate a recommendation that is essential to meet the currently accepted standards of protection. The word *should* indicates an advisory recommendation that is highly desirable and is to be implemented where possible. The word *patient* in this code describes a person being prescribed mammographic X-ray examinations for diagnostic purposes and includes a woman as a participant to a breast screening program. The term *medical physicist* in this code describes an individual who has received adequate training and is sufficiently experienced in radiation protection and the operation and testing of mammography X-ray equipment. In some jurisdictions, certifications or licensing may be required of the *medical physicist.*

In a field in which technology is advancing rapidly and where unexpected and unique problems continually develop, this Code cannot cover all possible situations. Blind adherence to rules cannot substitute for the exercise of sound judgement. Recommendations may be modified in unusual circumstances, but only upon the advice of experts with recognized competence in radiation protection and in

the operation of mammographic X-ray equipment. This Code will be reviewed and revised periodically, and a particular requirement may be reconsidered at any time if it becomes necessary to cover an unforeseen situation. Interpretation or elaboration on any point can be obtained by contacting the of Radiation Protection Bureau, Health Canada, Ottawa, Ontario, K1A 1C1.

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1. Introduction

Diagnostic X-ray imaging is an essential part of present day medical practice. In Canada, over 60 percent of the population undergoes radiological procedures each year. One of these radiological procedures is mammography, a valuable tool used in modern health care for the detection of breast cancer. It is the only detection modality proven reliable and effective in detecting preclinical breast cancer. However, mammographic X-ray procedures must be carefully managed, because X-radiation has the potential for damaging healthy cells and tissues, and great care must be taken to obtain optimal image quality for interpretation. The aim of radiation protection in radiology is to obtain the desired clinical information with minimum radiation exposure to patients, medical personnel, and the public.

During a properly carried out mammographic X-ray examination, the radiation dose received by an individual is generally low and relatively few cells are affected by the radiation. The body will replace or repair most, but not all, of the affected cells. Therefore, the effect of exposure to even low levels of ionizing radiation over long periods of time can accumulate and may represent a health risk. The need for radiation protection exists because exposure to ionizing radiation can result in deleterious effects that manifest themselves in the exposed individuals, and other effects that manifest themselves in their descendants. These are called somatic and genetic effects, respectively. Somatic effects are characterized by observable changes occurring in the body organs of the exposed individual. These changes may appear within a time frame of a few hours to many years, depending on the amount and duration of exposure of the individual. Genetic effects attributable to chromosomal damage of the germ cells giving rise to genetic defects are also a cause for concern at the lower doses used in diagnostic radiology. These genetic defects show themselves in the progeny of exposed individuals. The radiation doses may be low and appear to cause no observable damage, but genetic effects can be significant when considered for a large population. In mammography, the risk of genetic defects in well-conducted examinations is very small, and for post-menopausal women, there is no genetic risk.

It must be emphasized that it is not possible to measure carcinogenic effects at low doses and that estimates of the incidence of such effects are based on linear extrapolation from relatively high doses. It is generally accepted that there is no safe level of radiation dose and that no matter how low a dosage is used, there exists the probability of an effect. Since the projected effect of a low dose increases the incidence of a deleterious effect only minimally above the naturally occurring level, it is impossible to prove by observation either the validity or falsity of this hypothesis. However, the linear extrapolation hypothesis has been widely adopted in radiological protection and has led to the formulation of the ALARA (As Low As Reasonably Achievable) principle. This requires that a dose which can be reduced without significant loss of critical diagnostic information and without too much expense or inconvenience should be reduced, no matter how low it is and that a dose which can be avoided altogether, without unfavourable consequences, should be avoided.

With modern equipment and techniques, mammography is the most accurate diagnostic modality used in the detection of breast cancer. The two most common mammographic modalities presently in use are film-screen mammography and Xeromammography. Film-screen mammography utilizes low-energy X-rays with a compatible film-screen combination, and must be done using special dedicated mammographic X-ray equipment. To obtain consistent optimum image quality, a stringent Quality Control system is required for the entire diagnostic imaging chain, including X-ray equipment with consistent performance, good imaging techniques, appropriate loading factors, adequate image processing, and optimal viewing conditions. Xeromammography is a technique that uses X-ray tube voltages between 40 and 50 kVp and an electrostatic technique to record the image instead of film. In this technique, a selenium-coated positively charged plate is exposed to X-rays, and the X-ray photons cause the selenium to release electrons, neutralizing part of the positive charges. The plate is then processed and an image is obtained. As the image receptor is less efficient than a film-screen combination, glandular doses received by the patient are typically three to six times higher than those of film-screen mammography.

There are four main aspects of radiation protection to be considered in mammography. Firstly, patients should not be subjected to unnecessary radiographic procedures. Secondly, when a procedure is required, it is essential that the patient be protected from excessive exposure to radiation during the examination. Thirdly, it is necessary

that personnel in radiology facilities be protected from excessive exposure to radiation in the course of their work. Finally, personnel and the general public in the vicinity of such facilities require adequate protection.

In diagnostic mammography, the application of radiation protection begins with the request of the examination followed by the execution of the mammographic X-ray examination including positioning of the patient, irradiation, image processing and interpretation. In screening mammography, the application of radiation protection begins with the proper selection of participants followed by the execution of the mammographic X-ray examination. It is essential that close cooperation between radiologists, radiology technologists, medical physicists, and other support staff be maintained to obtain a consistent and effective level of radiation protection and image quality.

While dose limits have been established for radiation workers and the general public, these limits do not apply to doses received by a person as a patient undergoing diagnostic X-ray procedures. However, this Safety Code recommends limits on the mean glandular dose for a representative mammographic X-ray examination. Other limits may be recommended by Provincial standards where applicable. For patients, the risk involved with exposure to radiation must always be weighed against the clinical benefit of an accurate diagnosis, and there must always be a conscious effort to reduce patient doses to the lowest practical levels consistent with optimal image quality.

New modalities, such as stereotactic breast localisation, digital mammography, and storage phosphor mammography, are being introduced or are in development. While many characteristics and requirements for these modalities are comparable to the ones of film-screen mammography, there may be a need, in some situations, to modify requirements to suit these imaging modalities. Imaging procedures, where X-rays are not utilized, such as ultrasound, thermography, transillumination, and magnetic resonance imaging, are beyond the scope of this document.

2. Principal aims and scope of the Safety Code

This Safety Code is concerned with the protection of all individuals who may be exposed to ionizing radiation emitted by X-ray equipment used in the practice of mammography. The principal aims of this Safety Code are:

1. to minimize patient exposure to radiation consistent with obtaining images of optimal diagnostic quality during mammography;
2. to ensure adequate protection of personnel operating and maintaining mammographic X-ray equipment; and
3. to ensure adequate protection of other personnel and the general public in the vicinity of areas where mammographic X-ray equipment is used.

To assist in achieving these objectives, this Safety Code:

A. sets out the relative responsibilities of the owner, radiologist, radiology technologist, and medical physicist;

B. presents recommended practices for minimizing patient, personnel and general public exposure to radiation doses and for ensuring that mammographic X-ray equipment is used in a safe manner;

C. specifies minimum standards of design, construction and performance for mammographic X-ray equipment;

D. presents recommended practices to optimize image quality; and

E. supplies information required to implement and operate a Quality Assurance program for the facility.

3. Responsibility and personnel

Although staff responsibilities described below are grouped by each type of personnel or profession, to obtain the optimal level of radiation safety and image quality, it is imperative that full cooperation exists among all concerned parties.

3.1 Owner

The owner is ultimately responsible for radiation safety and image quality of a mammographic X-ray facility. It is the responsibility of the owner to ensure that the equipment and the facilities in which such equipment is installed and used meet all applicable radiation safety standards.

The owner may delegate this responsibility to staff. How this responsibility is delegated will depend upon how many staff there are, on the nature of the operation, and on the number of mammographic X-ray units owned. It is acceptable for facilities to have some of the duties listed assumed by suitable consulting bodies such as medical physics consulting organizations. In any event, one or more persons must undertake responsibility for:

1. ensuring that the installation complies with all applicable regulatory requirements; and that radiation levels are consistent with the recommended dose limits given in Appendix I;
2. consulting with the appropriate government agency(ies)
   i) when a new facility is being constructed, or modification of an existing one is planned, to ensure that radiation safety is adequate,
   ii) when mammographic X-ray equipment is purchased to ensure adequate radiation safety, and to register this equipment with the appropriate agency, and
   iii) to set periodic scheduled inspections for the facility. In some jurisdictions, the agency responsible for inspections has the mandate for setting inspection schedules;
3. establishing safe working conditions according to the recommendations of this Safety Code and the statutory requirements of Federal or Provincial legislation, where applicable;

4. ensuring that
   i) the equipment functions properly, and is maintained correctly by competent personnel,
   ii) safe operating procedures are established and are followed,
   iii) Quality Control monitoring of mammographic X-ray equipment, image processor, and ancillary equipment is carried out,
   iv) technologists are properly trained in the operation of the equipment being used, and
   v) technologists-in-training and inexperienced personnel operate mammographic X-ray equipment only under the direct supervision of a licensed or certified technologist;
5. implementing and maintaining an effective diagnostic imaging Quality Assurance program for the facility, including Quality Control and record keeping;
6. declaring who is to be considered an occupationally exposed person where this person may receive a radiation dose in excess of 1/20th of the recommended dose limit specified in Appendix I, keeping records of occupational exposures received by personnel, and investigating any exposure received by personnel in excess of 1/20th of the recommended dose limit; and
7. keeping records of radiation surveys, including summaries of corrective measures recommended and/or instituted, and organizing participation in a personnel radiation monitoring service, such as that provided by the Radiation Protection Bureau, Health Canada, Ottawa, Ontario, K1A 1C1; and
8. ensuring that personnel understand the contents of this Safety Code.

3.2 Radiologist

All radiologists must be licensed according to a recognized standard and must possess qualifications required by any relevant Federal and Provincial regulations or statutes. They must have received sufficient training in mammography and must receive continuing education. The radiologist must:

1. understand the contents of this Safety Code and follow the recommendations of Section 10;
2. communicate with staff any changes in image quality whether these changes are due to improper positioning, loading factors or image processing; and
3. participate fully in the Quality Assurance program.

3.3 Medical Physicist

The medical physicist is an individual who has received adequate training and is sufficiently experienced in radiation protection, and the operation and testing of mammography X-ray equipment. The medical physicist should be available to act as advisor on all radiation protection and diagnostic image quality matters during the planning stages, the construction of the facility, the installation of the equipment, and should also be available for consultation during regular operation of the facility. The medical physicist should have responsibility for:

1. verifying the safety of an installation at the time of planning and construction, and ensuring that the installation complies with all applicable regulatory requirements;
2. reviewing the safety procedures periodically and recommending to the owner the necessary changes to ensure optimum patient and personnel safety, and instructing personnel in proper radiation protection practices;
3. ensuring that
   i) the Quality Assurance program is properly implemented and operated,
   ii) the optimal level of diagnostic image quality is obtained, and
   iii) appropriate Quality Control monitoring instruments are available and properly calibrated;
4. performing the required testing of mammographic X-ray equipment, image processor, and ancillary equipment;
5. ensuring that all safety devices recommended by this Safety Code are functioning and that appropriate warning signs are properly located; and
6. understanding the contents of this Safety Code.

3.4 Quality Control Technologist

There must be a staff member who is responsible for the optimization of image quality. This person must have received adequate training in mammography Quality Control and in the operation of Quality Control test equipment. Depending on the size of the facility these duties can be performed by a staff X-ray technologist on either a part-time or full-time basis. The Quality Control Technologist should have responsibility for:

1. ensuring that the optimal level of diagnostic image quality is maintained;

2. performing daily and routine Quality Control tests of mammographic X-ray equipment, image processor, and ancillary equipment and keeping record of these tests;
3. communicating with staff any changes in image quality;
4. participating fully in the Quality Assurance program; and
5. understanding the contents of this Safety Code.

3.5 X-ray Technologist

All mammographic X-ray technologists must be certified according to a recognized standard, such as that of the Canadian Association of Medical Radiation Technologists, and must possess qualifications required by any relevant Federal and Provincial regulations or statutes. They must have received adequate training, and must receive continuing education in mammography techniques and procedures. If technologists are to perform special techniques such as mammography of patients with breast implants, they must also receive adequate training in these techniques. The technologists must:

1. understand the contents of this Safety Code and follow the recommendations of Sections 9 and 10.3;
2. be aware of the radiation hazards associated with their work and their duty to protect themselves, their patients, and others;
3. be aware of the consequences of improperly performed mammographic procedures on image quality and patient doses;
4. have a thorough understanding of their profession and of safe working methods; and
5. participate fully in the Quality Assurance program.

In general, there is no reason to remove pregnant technologists from their duties of operating mammographic X-ray equipment. However, it is advised that an X-ray technologist should immediately notify the employer if she suspects that she is pregnant, in order that appropriate steps may be taken to ensure that her work duties during the remainder of the pregnancy are compatible with the recommended dose limits specified in Appendix I.

4. Facility, equipment and installation requirements

In the planning of any mammographic X-ray facility, account must be taken of the operating X-ray tube voltage, the expected maximum workload of the equipment, and the occupancy factors for areas adjacent to the facility. Allowance should be made for possible changes in any one or all of these parameters, such as increases in operating tube voltage and workload, changes in equipment position, modification in techniques that may require ancillary equipment and an increase in the degree of occupancy of surrounding areas.

4.1 Facility design criteria

Certain basic principles must be observed when determining the shielding requirements for a room used routinely for diagnostic radiology. These are as follows:

i) the radiation levels in controlled areas that are occupied routinely by radiation workers must be such that no radiation worker is occupationally exposed to more than 20 mSv per year; and

ii) the radiation levels in uncontrolled areas must be such that no person can receive more than 1 mSv per year.

In general, radiation levels directly beside the image receptor of mammographic X-ray equipment are such that the above limits could be exceeded. However, because mammographic X-ray equipment uses low X-ray tube voltage, reduction in radiation intensity can be easily accomplished with the presence of a suitable shielding barrier between the patient and the technologist, a suitable combination of distance from the sources of radiation and shielding barriers, and restriction of persons from all areas in which the respective recommended dose limit could be exceeded.

The radiation shielding barriers required to reduce radiation levels below maximum permitted limits may be determined on the basis of distance, maximum expected X-ray tube voltage, workload, and occupancy factor. To ensure that the radiation levels are always below maximum permitted limits, the maximum possible workload should be used to calculate shielding requirements

during the planning stage of the facility. Also, due consideration should be given to possible future increases in occupancy factors.

Shielding calculations should be performed only by individuals with an in-depth knowledge of radiation protection requirements and radiation shielding barriers. When such calculations are required, contact the appropriate government agency. For installations under federal jurisdiction the responsible agency is the Radiation Protection Bureau, Health Canada, Ottawa, Ontario, K1A 1C1. Mammographic X-ray facilities that fall under provincial jurisdiction must meet the requirements of the responsible agency in their respective provinces. These requirements can be obtained by contacting the appropriate agency listed in Appendix IV.

4.1.1 General recommendations

Protection of the technologist and others near mammographic X-ray equipment should be achieved by:

1. operating mammographic X-ray equipment in a dedicated room designed for the purpose of mammography. The doors leading to the mammographic room from public areas should be equipped with self-closing devices;
2. ensuring that mammographic rooms are designed to provide adequate working space to allow for ease of patient movement, and ensuring that there is always an adequate shield between the patient and the technologist. If the radiation shield is not part of the mammographic X-ray equipment, an appropriate barrier allowing visibility of the patient must be provided;
3. shielding the floor, walls, ceiling and doors on the basis of distance, maximum expected X-ray tube voltage, and workload. The occupancy factors for the adjacent areas must be considered when calculations are made. Shielding must be constructed to form an unbroken barrier and shielding materials must be adequately supported;
4. positioning the control booth or mammographic X-ray equipment so that, during an exposure, no one can enter the room without the knowledge of the technologist;
5. using appropriate warning signs, which must be posted on the outside of all doors leading to each mammographic room. The warning signs must incorporate the X-radiation warning symbol specified in Appendix VII and should incorporate the words "Unauthorized Entry Prohibited";
6. arranging for the final plans of the installation to be reviewed by the appropriate responsible government agency when a new

facility is constructed or modification to an existing one is made. The plans and accompanying documents must show:

- the dimensions and shape of the room where the mammographic X-ray equipment is operated;
- the materials used to construct the walls, floor, ceiling, and the control booth, and their thicknesses including additional materials used in radiation shielding barriers;
- the positions of all windows, doors, louvres, etc., that may affect radiation protection requirements;
- the location and orientation of mammographic X-ray equipment;
- the location, use and accessibility of adjacent rooms, as well as rooms above and below the facility;
- the expected maximum workload;
- the brief description of the mammographic X-ray unit, containing at least the name of the manufacturer, model designation, operating X-ray tube voltages and X-ray tube current; and
- the location of the darkroom and film storage area.

4.1.2 Shielding recommendations

The thickness of lead, concrete or gypsum wallboard required to reduce radiation levels to the recommended dose limits can be determined through calculations. The following recommendations apply to mammographic facility shielding.

1. Planned and existing structural materials should be fully considered when calculating a barrier requirement.
2. For installations under federal jurisdiction, the shielding required must reduce dose to individuals in uncontrolled areas to 1 mSv per year and in controlled areas to 20 mSv per year. Mammographic X-ray facilities that fall under provincial jurisdiction must meet the requirements set by the responsible agency in their respective provinces. These requirements can be obtained by contacting the appropriate agency listed in Appendix IV.
3. Acoustical type lead is not suitable for lead shielding.
4. For mammographic X-ray equipment, the image receptor support intercepts most, but not all of the primary X-ray beam. Therefore, there may be a need for primary barrier shielding for some specific areas of the room.
5. For secondary barriers shielding, the orientation factor is always equal to 1.

6. To determine the shielding necessary for a mammographic facility, the following information is required:
   - the distance between the nearest point of the area to be shielded;
   - the usual location and position of the X-ray unit;
   - the area designation (controlled or uncontrolled), (primary or secondary);
   - occupancy factors of adjacent rooms;
   - the maximum operational X-ray tube voltage;
   - the location of the darkroom and film storage area; and
   - anticipated maximum workload of the mammographic X-ray unit (in milliampere-minutes per week).

4.2 Equipment purchase

All new, used and refurbished medical X-ray equipment, and accessories, purchased or leased in Canada must conform to the requirements of the Radiation Emitting Devices Act and Regulations. Mammographic X-ray equipment must comply with Radiation Emitting Devices Regulations, Part XII: "Diagnostic X-ray Equipment", and it is the responsibility of the manufacturer or distributor to ensure that the equipment conforms with the requirements. The appropriate sections of this regulation are reproduced in Appendix VII of this Safety Code. In addition, all mammographic X-ray equipment must meet provincial requirements established for such equipment. The Canadian Standards Association and provincial electrical utility should be consulted for further information.

4.2.1 Performance specification writing

During the purchasing process, performance specifications for the mammographic X-ray equipment and accessories such as film cassettes and screens must be prepared with the full knowledge of the clinical needs, operational conditions and requirements, manufacturer's specifications, and regulatory requirements. The level of performance should be such that most manufacturers should be able to meet these performance requirements with readily available components and product lines.

Testing equipment not already available and required to perform Quality Control procedures must be purchased at the same time as the mammographic X-ray unit. Only testing equipment which is to be used by the facility needs to be purchased. This equipment is described is Section 8.1.

The performance specifications should include all relevant requirements stated in Section 5.3 and any further requirement as specified by the agency responsible for the facility. The performance specifications should include relevant electrical, mechanical and environmental conditions which may affect the performance of the equipment.

4.2.2 Acceptance testing

Acceptance testing must be performed before any clinical use of the equipment. Acceptance testing is a process to verify compliance with the performance specifications of the mammographic X-ray equipment as written in the purchase agreement. It must also verify that the equipment performance meets the manufacturer's specifications and complies with federal and provincial regulations. It is recommended that acceptance testing be performed by a medical physicist, or other individual knowledgeable in mammographic X-ray equipment testing and relevant regulations. For mammographic X-ray equipment, the federal regulation is the Radiation Emitting Devices Regulations, Part XII and is stated in Appendix VII. Acceptance testing of a mammographic system includes several major steps. They are:

1. the verification that delivered components or systems correspond to what was ordered;
2. the verification of the system mechanical integrity and stability, including safety mechanism, automatic patient release, power drives, interlocks;
3. the verification of electrical installation, including electrical safety, powerline fluctuation; and
4. the verification of mammographic X-ray performance.

X-ray performance tests performed during the acceptance testing should also reflect the requirements described in Section 5.3. In addition, the testing must evaluate the image quality produced by the X-ray system and determine typical surface and glandular dose. The results from the acceptance testing should be used to set baseline values and limits on operational performance of the mammographic X-ray equipment. These baseline values and limits are essential to the Quality Assurance program.

4.3 Radiation protection inspection

Radiation protection inspections must be established on a regular basis to assess that:

1. the mammographic X-ray equipment functions properly and according to applicable standards and legislative requirements;
2. the mammographic X-ray equipment is installed in a safe environment and is used in a way which provides maximum radiation safety for patients, technologists, and the public;
3. an adequate Quality Assurance program is properly implemented and maintained; and
4. the level of diagnostic image quality is optimized and maintained.

For installations under Federal jurisdiction the responsible agency is the Radiation Protection Bureau, Health Canada, Ottawa, Ontario, K1A 1C1. Mammography facilities that fall under provincial jurisdiction must meet the requirements of the responsible agency in their respective provinces. These requirements can be obtained by contacting the appropriate agency listed in Appendix IV.

5. Equipment specifications

5.1 Newly purchased medical X-ray equipment

All new, used, and refurbished mammographic X-ray equipment, and accessories for such equipment, which is sold, imported or distributed in Canada, must conform to the requirements of the Radiation Emitting Devices Act and the Food and Drugs Act and their promulgated regulations. These are the Radiation Emitting Devices Regulations and the Medical Devices Regulations. The Radiation Emitting Devices Regulations specify standards of design, construction and performance, with respect to radiation safety. The Medical Devices Regulations encompass all other safety considerations and the question of efficacy for all medical X-ray equipment sold in Canada. It is the responsibility of the manufacturer or distributor to ensure that the equipment conforms to the requirements of these regulations.

The Radiation Emitting Devices Regulations in effect and relevant for mammographic X-ray equipment, at the time of printing of this Safety Code, are reproduced in Appendix VII. These regulations may be amended, from time-to-time, to keep up-to-date with changing technology in the field. Information on the applicability and currency of the Radiation Emitting Devices Regulations may be obtained by contacting the Radiation Protection Bureau, Health Canada, Ottawa, Ontario, K1A 1C1.

In addition, mammographic X-ray equipment must meet any applicable requirements under provincial jurisdictions for such equipment.

5.2 Existing medical X-ray equipment

When possible, existing mammographic X-ray equipment must be upgraded to incorporate as many as possible of the safety and performance features required of new mammographic X-ray equipment. It should be noted that it is a requirement of the Radiation Emitting Devices Regulations that replacements for any component or subassembly of an X-ray machine, for which a design, construction

or performance standard has been specified in the Regulations applicable to the class of X-ray equipment, must comply with the standards in effect at the time of replacement.

Only equipment designed specifically for mammography shall be used, and to ensure maximum protection for patients and staff, all existing mammographic X-ray equipment must at least meet certain basic requirements. These requirements are itemized in the remainder of this Section.

5.3 General requirements for mammographic X-ray equipment

The following requirements must be met by all mammographic X-ray equipment. Specific requirements for film-screen mammographic X-ray equipment are listed in Section 5.3.1, whereas requirements for Xeromammographic X-ray equipment are listed in Section 5.3.2.

1. *Warning Signs* – The X-ray control panel must bear a permanent and conspicuous sign warning that hazardous X-radiation is emitted when the equipment is in operation and prohibit unauthorized use.
2. *Markings* – All controls, meters, lights and other indicators relevant to the operation of the equipment must be readily discernible and clearly labelled or marked as to function.
3. *Focal Spot Marking* – The location of the focal spot must be clearly and accurately marked on the X-ray tube housing. In the case of dual focus X-ray tubes, the location of the mark should be midway between the centres of the two focal spots.
4. *Indicator lights* – There must be readily discernible, separate indicators on the control panel that indicate:
   i) when the control panel is energized and the machine is ready to produce X-rays, and
   ii) when X-rays are being produced.
5. *Indication of Loading Factors* – For mammographic X-ray equipment having adjustable loading factors, the control panel must incorporate electrical meters or other indicators that enable determination of the X-ray tube voltage, X-ray tube current and time, or combinations of these. For equipment having non-adjustable loading factors, permanent marks or labels may be used to indicate these parameters. The loading factors should be displayed after the irradiation is complete.

If the mammographic X-ray equipment is battery-powered, there must be a visual indicator that shows whether the battery is adequately charged for proper operation.

6. *Irradiation Control* – There must be an irradiation switch, or other device to initiate and terminate X-ray production. The irradiation switch must require continuous pressure by the operator to produce X-rays.
7. *Timer* – A timing device must be provided to automatically terminate the irradiation. The timer must be designed and constructed in such a way that it is not possible to energize the X-ray tube without automatic or manual resetting of the timer after each loading, that an irradiation cannot be initiated with the timer set at its zero or OFF position and the production of X-rays is automatically terminated after a preset time, preset milliampere-second value, or a preset exposure or air kerma value. The timing device must be accurate to 1/60 second or to 7 percent, whichever is greater.

   A backup timer must be provided to limit the product of the X-ray tube current and the irradiation time during an irradiation. The product of the X-ray tube current and the irradiation time must not exceed 2,000 milliampere-seconds per irradiation. When possible, the product of the X-ray tube current and the irradiation time should be set not to exceed 1,200 milliampere-seconds per irradiation.
8. *X-ray Tube Shielding* – The X-ray tube must be enclosed in a shielded housing. The shielding of the housing must be such that, at every rating specified by the manufacturer, the leakage radiation does not exceed 17.5 μGy (2 mR) per hour at 5 cm from any point on the external surface of the housing.
9. *Beam Limiting Devices* – Suitable beam limiting devices capable of restricting the radiation beam shall be provided and shall provide the same attenuation as the X-ray tube housing. The beam limiting device should be designed in such a way that, for any focal spot to image receptor distance, the radiation beam does not extend beyond the edge of the image receptor except at the edge adjacent to the chest wall where the X-ray field shall not extend beyond the edge by more than 2 percent of the focal spot to image receptor distance.

   If a light localizer designed to define the outline of the X-ray field is included, the misalignment, in the plane of the image receptor,

of the light field with respect of the X-ray field along either length or width must not exceed 2 percent of the source to image receptor distance (SID).

10. *Image Receptor Support Shielding* – The image receptor support shall transmit less than 0.87 μGy (0.1 mR) per irradiation at all operating loading factors at the minimum source to image receptor distance.
11. *Breast Compression Device* – A device to maintain firm breast compression shall be provided on the mammographic X-ray equipment. This device must provide adjustable, uniform and constant compression of the breast during mammography. The X-ray beam attenuation of the compression plate should be less than that of 2.5 mm of polymethylmethacrylate (PMMA) equivalent. There is no known optimal value of compression. However, a minimum of 20 kg should be generated but compression forces of 25 kg or greater should be achievable only with manual control.

    The breast compression device should not produce inhomogeneities or artifacts which can degrade image quality.

    The deformation of the breast compression device at maximal compression force should not be greater than 15 mm at each corner between the surface of the image receptor system and the breast compression device when a piece of foam rubber is compressed.
12. *Protective Barrier* – A protective radiation barrier shall be provided. This barrier must allow the technologist to observe the patient during the entire procedure and should provide attenuation equal to or greater than 0.25 mm Pb equivalent at 50 kVp. The barrier should be at least 0.6 m wide and 1.85 m high and reach within 0.15 m above the floor.
13. *Mechanical Stability* – The X-ray tube must be securely fixed and correctly aligned within the tube housing. The X-ray tube housing must maintain its required position without drift or vibration during operation and must be balanced to provide smooth operation.

5.3.1 Requirements for film-screen mammographic X-ray equipment

1. *Target Material* – Molybdenum (Mo) or Molybdenum-Tungsten (Mo-W) alloy target X-ray tubes shall be used for film-screen mammographic X-ray equipment. Alternate target material may be appropriate when used with alternate filter material provided that it produces comparable image quality at equal or reduced dose to the breast.
2. *Focal Spot Size* – The focal spots must be small enough not to create excessive geometric unsharpness. The focal spots should be measured using either a slit camera, the pinhole method, or other method where the nominal focal spot size can be determined. For film-screen mammographic X-ray equipment, the nominal focal spot size should be:

   equal to or less than 0.40 mm for contact or grid techniques at 65 cm SID,
   equal to or less than 0.30 mm for contact or grid techniques at 50 cm SID,
   equal to or less than 0.15 mm for 1.5 magnification,
   equal to or less than 0.10 mm for 2.0 magnification.

3. *X-ray Beam Filtration* – A permanent filter of about 0.025 to 0.030 mm Mo shall be permanently installed. For magnification, a Tungsten target microfocal-spot X-ray tube may be used and this tube shall have at least 0.5 mm Al equivalent total filtration. Alternate filter material may be appropriate provided that it produces comparable image quality at equal or reduced dose to the breast.
4. *Radiation Beam Quality* – There must be radiation-absorbing filters that provide a degree of attenuation such that the first Half-Value Layer of aluminum is not less or greater than the values shown in Table 1 for a selected X-ray tube voltage. For other X-ray tube voltages, the Half-Value Layer of the radiation beam must be calculated by linear interpolation from that Table. Half-Value Layer measurements must include the attenuation of the breast compression device if the device is of uniform thickness and without holes.

Table 1:
Acceptable Half-Value Layer for
Mo or Mo-W alloy target X-ray tube

X-ray Tube Voltage (kilovolt)	First Half-Value Layers (minimum – maximum) (millimetre of Al)
24	0.24 – 0.34
26	0.26 – 0.36
28	0.28 – 0.38
30	0.30 – 0.40
35	0.35 – 0.45

5. *X-ray Tube Voltage* – The X-ray tube voltage should be adjustable in 1 kVp increments. The lowest selectable X-ray tube voltage shall be equal to or less than 24 kVp. The peak X-ray tube voltage should correspond to within 5 percent of the selected or indicated value. The X-ray tube voltage reproducibility should be within 2 percent.
6. *X-ray Tube Radiation Output* – The X-ray tube radiation output shall be high enough to minimize irradiation time to eliminate perceptible motion artifacts and reduce the dose to the patient resulting from reciprocity law failure of film-screen combination. The X-ray tube output should be at least 4.4 mGy/s (500 mR/s) at 28 kVp.

   For any combination of operating loading parameters, the coefficient of variation of any ten consecutive radiation exposure measurements, taken at the same source to detector distance within a time period of one hour, is no greater than 0.05, and each of the ten radiation exposure measurements is within 15 percent of the mean value of the ten measurements.
7. *Automatic Exposure Control* – An Automatic Exposure Control (A.E.C.) system must be provided. The system should be able to maintain a net film density of ±0.15 O.D. (Optical Density) units within a range of 1.0 to 1.5 O.D. for a film with an average gradient of 3.0 O.D., for the range of breast thicknesses examined, and for all types of technique (non-grid, grid, and magnification) and loading factors used by the facility. In

addition, a film density control for the A.E.C. should be provided with each increment increasing or decreasing film-screen cassette dose by 20 percent.

When manual irradiation control is used, the selectable control interval (time or mAs) shall be small enough to permit increments smaller than 25 percent.

8. *Breast Support Table* – The attenuation of the breast support table should not exceed 0.3 mm Al equivalent at 30 kVp.
9. *Anti-scatter Grid and Bucky System* – If an anti-scatter grid or Bucky system is used, it must be designed for mammographic purposes and must not produce inhomogeneities or artifacts which can degrade image quality. Grid lines should not be visible on mammograms.

5.3.2 Requirements for Xeromammographic X-ray equipment

1. *Target Material* – For Xeromammographic X-ray equipment, a Tungsten (W) or Molybdenum-Tungsten (Mo-W) alloy target X-ray tube with Aluminum (Al) filtration shall be used. Alternate target material may be appropriate when used with alternate filter material provided that it produces comparable image quality at equal or reduced dose to the breast.
2. *Focal Spot Size* – The focal spots must be small enough not to create excessive geometric unsharpness. The focal spots should be measured using either a slit camera, the pinhole method, or other method where the nominal focal spot size can be determined. For Xeromammographic X-ray equipment, the nominal focal spot size should be:

   equal to or less than 0.6 mm for contact techniques at 80 cm SID,
   equal to or less than 0.5 mm for contact techniques at 65 cm SID,
   equal to or less than 0.20 mm for 1.5 × magnification,
   equal to or less than 0.15 mm for 2.0 × magnification.

3. *X-ray Beam Filtration* – For Tungsten target X-ray tube, the total filtration shall not be less than 2.0 mm Al equivalent at 50 kVp, and for Molybdenum-Tungsten target X-ray tube, the total filtra-tion shall not be less than 1.6 mm Al equivalent at 50 kVp. Alternate target material may be appropriate provided that it produces comparable image quality at equal or reduced dose to the breast.

4. *Radiation Beam Quality* – There must be radiation attenuating filters that provide a degree of attenuation such that the first Half-Value Layer of aluminum is not less or greater than the values shown in Table 2 for a selected X-ray tube voltage. For other X-ray tube voltages, the Half-Value Layer of the radiation beam must be calculated by linear interpolation from that Table. Half-Value Layer measurements must include the attenuation of the breast compression device.

Table 2:
Acceptable Half-Value Layer for W or Mo-W alloy target with Al filter

X-ray Tube Voltage (kilovolt)	First Half-Value Layers (minimum – maximum) (millimetre of Al)
Tungsten target	
40	0.40 – 1.50
49	0.50 – 1.60
Molybdenum-Tungsten target	
40	0.40 – 0.90
49	0.50 – 1.00

5. *X-ray Tube Voltage* – The X-ray tube voltage should be adjustable in 2 kVp increments. The lowest selectable X-ray tube voltage shall be less than or equal to 40 kVp. The peak X-ray tube voltage should correspond to within 5 percent of the selected or indicated value. The X-ray tube voltage reproducibility should be within 2 percent.
6. *X-ray Tube Radiation Output* – The X-ray tube radiation output shall be high enough to minimize irradiation time to eliminate perceptible motion artifacts.

   For any combination of operating loading parameters, the coefficient of variation of any ten consecutive radiation exposure measurements, taken at the same source to detector distance within a time period of one hour, is no greater than 0.05, and each of the ten radiation exposure measurements is within 15 percent of the mean value of the ten measurements.

7. *Automatic Exposure Control* – An Automatic Exposure Control (A.E.C.) system should be provided. The system should be able to maintain the dose to the cassette to within 15 percent of the nominal value for the range of breast thicknesses examined and for all types of technique and loading factors used by the facility. In addition, a density control should be provided with each increment increasing or decreasing cassette dose by 25 percent.

   When manual irradiation control is used, the selectable control interval (time or mAs) shall be small enough to permit increments of 25 percent.

6. Image processing and handling

The irradiation necessary to produce a mammogram of satis-factory diagnostic quality with minimum radiation dose to the breast depends on the loading factors, film-screen employed, the handling and processing of the film, and on the conditions of viewing the image. It is essential that automated processing be used to develop mammographic films. It is also highly recommended that the image processor be dedicated for mammographic use only. Good image quality requires proper darkroom techniques, routine processor Quality Control monitoring, and careful adherence to film and processor manufacturers' instructions.

6.1 Film processing

Improper or careless processing of exposed mammographic films can result in poor diagnostic image quality and consequently increase the possibility of wrong diagnosis or the need for repeat mammographic X-ray examinations. To achieve full development, the film must be processed in chemically fresh developer, at the correct temperature and for sufficient time to ensure that the silver in exposed silver halide crystals in the film emulsion is completely reduced. If this is not done, the blackening of the film will not be optimum and the tendency will be to increase irradiation to achieve proper image density.

Other factors can also affect the quality of the processed film. These include cleanliness of the processing system, film immersion time, and the efficiency of the rinsing. The use of automatic film processing equipment will produce films of more uniform density with the possibility of lower patient dose than by using manual processing. Manual film processing shall not be used in mammography. To ensure proper processing of films certain basic procedures must be followed:

1. The only acceptable method to monitor the operation of an automated image processor is with the use of a sensitometer to produce repeatable light exposure of the film and with the use of a densitometer to monitor the processed sensitometric film. Processor monitoring must be done every morning when the processor is started and has stabilized, and at additional times after the processor has been cleaned, or a few hours after fresh chemical has been added to the replenisher tanks. The processor should be given sufficient time to stabilize, before mammographic procedures are performed on patients.
2. Manufacturers' recommendations with respect to strength of solution, temperature and time must be followed to ensure optimum development.
3. Developing solutions must be replenished as necessary and must be changed or recycled regularly, as required. This should be done often enough to avoid oxidation of the developing solutions. Even unused developer deteriorates with time. Processing chemicals must be protected from freezing. Manufacturers' recommendations should be followed in storing chemicals to avoid oxidation, any chemicals showing signs of oxidation or sedimentation must not be used.
4. Fixer must be adequately removed from processed films. Manufacturers' recommendations for film wash should be followed. Fixer retention tests should be done on a regular basis.
5. Cleanliness is extremely important for reducing film artifacts. The film transport mechanisms of film processors must be cleaned frequently. Abrasive cloths or cleaners should never be used on mammographic processors.
6. Film processors must be maintained regularly, in accordance with the manufacturers' instructions. The accuracy of the processor thermometer should be checked regularly with a non-mercury thermometer. A digital processor thermometer should be accurate to within 0.5°C.
7. When film processing volume is less than 50 films per day, it may not be possible to adequately control chemical concentrations. In this situation, it is preferable to use flood replenishment to better control chemical concentrations.

8. In some situations, it is possible to reduce patient dose by extending processing time. It is important to make sure that image quality is not reduced when using this processing method.

6.2 Darkroom

With the exception of daylight automatic image processors not requiring darkrooms, automatic film processors require properly designed darkrooms. While specific details may vary from installation to installation, all darkrooms must include certain basic features:

1. The room must be light-tight. Particular attention must be paid to the door seal and the mounting of the film processor if the film insertion to the processor is done through a wall. The darkroom should incorporate a lockable door, double doors or a blackened maze entrance to ensure light-tightness when undeveloped films are being handled. A film strip exposed to an optical density of 1.2 units must not show an increase in optical density greater than 0.05 units in two minutes exposure to the darkroom light environment.
2. If the darkroom is adjacent to a radiographic room, the film storage container must be adequately shielded to ensure that excessive exposure of film by X-rays does not occur. Film shielding is specified in Appendix III.
3. A warning light should be located outside the darkroom, at the entrance, to indicate when the room is in use. The warning light is not required if the door is locked when it is closed.
4. Safelights, fitted with bulbs of intensity not greater than 15 watts, must be provided above the work areas inside the darkroom. The safelight must have filters appropriate to the specifications of the film used and must be positioned at distances greater than 1 metre from work areas to minimize film fogging.

6.2.1 Darkroom maintenance

Cleanliness in the darkroom and of the screens and cassettes is essential. It is important to maintain the cleanest environment possible in order to minimize any artifacts caused by dirt, dust, or improper handling of film. An ultraviolet light should be used to find dust areas around the darkroom. No one should eat, drink or smoke in the darkroom area. All working surfaces, tops of counters and the floor should be cleaned regularly, at least once a day. Tops to cabinets,

vents, light fixtures and any other areas which can collect dust should also be cleaned on a regular basis. The ventilation system should be checked to make sure that no dust is carried from it to inside the darkroom; any filter should be changed on a regular basis. If possible, the darkroom should be under positive pressure so that chemical fumes and dust are not sucked into the room when the door is opened. The number of air changes should be high enough for the processor to operate properly and to not create a hazardous situation for personnel. Chemicals should not be mixed inside the darkroom since this operation can result in chemical splashes onto the equipment or working surfaces.

To avoid putting fingerprints on the film and to avoid dirtying the screens, it is important to wash the hands frequently with soap that does not leave any residue. Clutter which may collect dust should be eliminated. Corrugated cardboard boxes containing film boxes, chemicals, and other supplies should not be stored or opened inside the darkroom; opening corrugated cardboard boxes creates a lot of dust. The boxes should be opened outside the darkroom, and films and supplies carried inside. Any articles of clothing made of loose fibres or static-generating such as wool, silk, some cottons or cotton blend fabric should not be worn in the darkroom or should be covered with a laboratory coat.

6.3 Mammographic X-ray film

Mammographic X-ray films are sensitive to light, heat, humidity, chemical contamination, mechanical stress and X-radiation. Unexposed mammographic film must be stored in such manner that it is protected from stray radiation, chemical fumes and light. The level of optical density from the base material and film fog from all causes must not be greater than 0.2 units.

Storage should be provided so that no film receives more than 1.75 μGy (0.2 mR) of radiation before use. The amount of shielding required will depend on the storage time and on the workload of the facility. For the majority of facilities 1.0 mm of lead shielding will be adequate.

Generally, mammographic X-ray films should be stored at temperatures in the range of 10°C to 21°C with humidity between 30 percent to 60 percent. It is advisable to follow film manufacturers' instructions. It is recommended that film be stored on edge in an area away from chemical fumes. Allow sealed film packages to reach room temperature before opening to prevent condensation on the films.

Loaded cassettes must be stored in an area shielded from exposure to radiation. This area is usually in or near the mammographic X-ray room. The location of exposed and unused cassettes must be clearly marked. The area should be large enough to accommodate the required supply of cassettes needed during the operation of the facility.

6.4 Viewbox

The condition of viewboxes should be checked regularly. The conditions under which radiologists and other health care professionals examine mammograms may influence diagnostic accuracy. Problems with improper illumination due to the non-uniformity of fluorescent tube manufacture, degradation and the discoloration of the viewing surface must be corrected. Illumination should be constant between all boxes used to read mammograms. The viewing conditions including ambient light level and film masking are as important as the actual luminance of the viewing box. Ambient and extraneous light should be reduced to a minimum since a very bright viewing box is necessary when the ambient light level is high. It is best to use only one type of fluorescent tube within a facility; these tubes should be changed when signs of aging develop. Care should be taken to clean the viewing surface of the viewbox such that no dirt could influence diagnostic accuracy.

There is no optimal level of illumination for viewboxes. However, the viewbox brightness should be at least 3000 nits (cd/m^2). The light output from the viewboxes should be uniform to within 10 percent and the light output homogeneity between all viewboxes used for mammograms should be uniform to within 15 percent. The ambient light within the reading room should be less than 50 lux.

6.5 Cassette and screen

Cassettes or screens in poor condition will impair diagnostic quality. Problems are caused by dirty or damaged screens, warped cassettes, fatigue of foam compression material or closure mechanism, light leaks, and poor film-screen contact. Cassettes should be checked regularly for wear, and cleanliness. Manufacturer recommended screen cleaner should be used. To avoid artifacts caused by dirt and dust, the intensifying screens and cassettes should be cleaned at least weekly. The cassette holder tunnel should be checked regularly for dirt and dust. The intensifying screens should be inspected with an ultraviolet light to find dust particles. Cleaning tools include a screen cleaner with antistatic solution, lint-free cloths, compressed air, and a camel hair brush.

There must be no region of poor contact between the film and the screen greater than 1 cm^2 where image is present or greater than 2 mm wide 1 cm long at the chest wall. The film optical density must be within ±0.15 units for all cassettes used in the facility when tested with identical loading factors.

The proper amount of filtration placed in the X-ray beam between the X-ray tube and the patient reduces radiation exposure to the patient. However, any material placed between the patient and the mammographic image receptor has the effect of increasing patient exposure. With this in mind, only cassettes specifically designed for mammographic use must be used. Cassettes intended for general radiographic purpose must never be used in mammography.

Cassettes and screens should be numbered for identification and matching. The preferred location for marking is on the long side away from the chest wall.

7. Quality Assurance program

Quality Assurance in mammography is defined as the planned and organized actions necessary to provide confidence that mammographic X-ray equipment and related components operated in a facility will reliably produce quality mammograms with minimum dose to patients and staff. This means that the radiologist and other health care professionals will be provided with images of diagnostic quality with the least amount of radiation for the examination. A Quality Assurance program for mammography includes Quality Control procedures for the monitoring and testing of mammographic X-ray equipment and related components, and administrative methodology to ensure that monitoring, evaluation and corrective actions are properly performed. A Quality Assurance program shall include all practices established by the owner to ensure that:

i) the mammographic X-ray examination is performed with the lowest possible radiation dose to the patients consistent with clinical diagnostic requirements;

ii) the mammograms produced provide for accurate clinical assessment; and

iii) all steps leading to accurate diagnosis are taken and the information is made available in a timely fashion to the patient's physicians.

7.1 Goals of Quality Assurance program

The principal goal of a Quality Assurance program is to ensure accurate and timely diagnosis. The secondary goal is to minimize radiation dose to the patient as long as the principal goal is achieved. Two factors will affect the operation of a Quality Assurance program; one deals with the diagnostic imaging equipment and the other with equipment operation. It is essential that the equipment be in proper working condition if any Quality Assurance program is to succeed. All staff members must participate fully in the implementation and operation of the Quality Assurance program, and must understand the goals of the program and must be committed to the concept. Any program initiated only to comply with regulatory requirements is not likely to provide the maximum possible benefit to the patient.

Mammograms of diagnostic quality must contain all information necessary for the diagnosis. If critical elements are missing from the mammogram or artifacts are added to it, the image is considered to be of poor quality. False positive mammograms result in unnecessary anxiety for the patient whereas false negative mammograms provide a false sense of security. The consequence of poor quality mammograms may be incorrect diagnosis resulting in possible premature death of the patient, unnecessary biopsies, repeat mammographic procedure, unnecessary radiation dose to the patient, and increased cost.

7.2 Cost-benefit of Quality Assurance program

The initial implementation along with the general operation of a Quality Assurance program in mammography will involve cost in both time from staff and money. However, savings from the operation of the program will offset some of these costs. For some facilities, there may be a reduction in overall operating costs. Some of the costs associated to the Quality Assurance program are as follow.

1. *Personnel* – The staff will be required to perform new duties, which include generating test images for their mammographic X-ray equipment and record keeping. It is expected that staff cost beyond the initial cost, including training, incurred during the implementation of the program would be minimal.
2. *Test equipment* – Test equipment for photographic, radiographic and diagnostic image Quality Control, such as mammographic phantoms, will be required. However, the cost of such equipment is small compared to the cost of mammographic X-ray equipment and it can be utilized for several mammographic X-ray systems. It would not be necessary to purchase some of the test equipment if the facility decides to have some of the Quality Control tests performed by an external organization or individual.
3. *Test images* – Two to five percent of films used by a facility may be required for the performance of sensitometry, phantom imaging, equipment and cassettes testing.
4. *External organizations* – If the facility does not have the capacity to perform internally all Quality Control tests, it may choose to contract an external organization or individual to perform some

of these tests and equipment assessment. In addition, the facility may retain the service of a medical physicist as an advisor during implementation and for consultation during operation of the facility.

In addition to improved diagnostic quality of mammograms, some of the savings associated to the Quality Assurance program are as follow.

A. *Film and processing chemicals* – A decrease in the number of retakes may result in the reduction in the number of mammographic films and processing chemicals used.
B. *Equipment* – The reduction in the number of mammograms taken will lead to a reduction in workload which in turn will put less stress on mammographic X-ray equipment and image processors. Problems with equipment may be diagnosed earlier before more serious and costly problems occur thus reducing down time and equipment service cost.
C. *Patient flow* – The reduction in the number of repeated mammograms, and better diagnostic quality of the mammograms will allow efficient use of time for both radiologists and technologists. This will result in better predictability of scheduling and possibly greater patient throughput.

7.3 Implementation of a Quality Assurance program

The implementation of a Quality Assurance program in mammo-graphy need not be complicated. It consists in establishing Quality Control procedures for the equipment along with an administrative methodology to ensure that monitoring, evaluation and corrective actions are properly performed.

7.3.1 Establishment of Quality Control procedures

The following four steps are needed for the establishment of Quality Control procedures.

1. *Equipment operation* – It is essential that mammographic X-ray equipment and image processing equipment function properly before a Quality Assurance program is implemented. Manufacturer and vendor should provide proper operating characteristics for their equipment. Film-screen combination and processing should meet manufacturer's speed and contrast values. This may involve replacement, repair, upgrading or calibration of the equipment.

2. *Baseline performance* – Baseline performance values of mammographic X-ray equipment and image processing system must be established after verifying that equipment functions properly. This baseline performance will be used to diagnose any changes in equipment performance. It is important to keep records of equipment operation data and baseline performance measurement. These records will be needed to diagnose any changes in image quality.
3. *Reference test image* – To evaluate image quality of mammograms, a reference test image is needed. This reference test image is made by using the mammographic X-ray equipment, image processing system and a mammographic phantom and will be used for comparison of daily test image.
4. *Result evaluation and action levels* – An effective Quality Control monitoring program includes not only a routine Quality Control testing schedule, data recording and record keeping, but also test result evaluation, such as determination of acceptable or unacceptable limits of equipment operation coupled with a list of corrective actions that may be required.

A set of limits should be established which indicates a level of operation outside of which the system or the function should be closely monitored but where no immediate action is required. Another set of limits should also be established where immediate remedial action must be taken.

7.3.2 Establishment of administrative procedures

The following administrative procedures are needed for an effective Quality Assurance program.

1. *Responsibility* – Although the owner of the facility is ultimately responsible for the implementation and operation of the Quality Assurance program, to obtain the optimal level of radiation safety and image quality, it is imperative that full cooperation exist between all concerned parties. Staff members may be assigned duties with regard to equipment monitoring, record keeping and Quality Assurance operation. It is essential that the level of responsibilities and involvement of the owner and staff be indicated and understood.
2. *Record keeping* – It is essential that measurements and information gathered for the Quality Assurance program be clearly documented and readily available for evaluation. As far as practicable, recorded data should be indicated as data points on

a control chart when the measurement is made. For example, it includes the densitometric results of the sensitometric film strips and the charting of temperature for the film processor. In this form, trends can be more easily detected. A log book or other easily identifiable method of recording must be used.

3. *Evaluation of data* – Recorded data should be evaluated immediately and necessary actions taken.
4. *Limits of acceptability of data* – Upper and lower limits of acceptability of recorded data must be determined and documented. When these limits are reached, corrective actions must be taken. For example, they can be the range of acceptable temperature for the film processor. These limits should be set such that they are just within the range allowable before diagnostically significant image changes are evident. They should not be so restrictive that they exceed the capability of the equipment, or that frequent corrective actions are taken without any evidence of problems. These limits should be reviewed from time to time.
5. *Testing frequency* – Testing frequency must be such that a balance is reached between the cost of testing, the disruption to the operation of the facility and the maintenance of quality.

   The frequency of testing should be increased if the equipment exhibits significant changes between scheduled Quality Control tests, or if the equipment is used for exceptionally high volume of procedures. Additional testing should be performed if the results of testing fall outside the limits of acceptability for the tests, or after any corrective actions are made. Equipment must be retested after service to any part which may affect the image density, image quality or radiation output from the X-ray tube.

   The Quality Control program should not be discontinued if the results indicate relatively stable equipment performance. The purpose of a Quality Control program is to control quality, and periodic measurement of equipment performance is essential. The frequency of testing described in Section 8 should be considered a minimum.

6. *Corrective actions* – There must be established repair and calibration procedures to deal with significant problems. A decision tree system should be developed to provide guidance to deal with events such as equipment failure and to deal with circumstances when equipment performance deviates beyond the set limits. A list of individuals having the the authority to stop operation of a mammographic unit should be established. The decision tree should include the following steps:
   i) repeat test to confirm;
   ii) what to do if repeated test confirms performance failure;
   iii) what to do if test fails only marginally;
   iv) what to do if test shows a history of failure; and
   v) what to do if test fails substantially.

8. Quality Control procedures in mammography

There are two types of Quality Control procedures in mammography. Initially, there are procedures performed at the implementation of the Quality Assurance program. Subsequently, there are procedures carried out during the operation of the program. Consultation with a medical physicist or an expert in Quality Assurance for mammography should be done from time to time to reassess the operation of the program.

8.1 Quality Control equipment

It is essential that the necessary Quality Control test equipment be provided to the Quality Control technologist or medical physicist. It is suggested that the required test equipment be acquired when mammographic X-ray equipment is purchased. It is also important that the Quality Control technologist or medical physicist be trained in the proper use of the test equipment.

If the facility elects to perform all Quality Control tests including testing carried out during implementation of the program to establish baseline values, daily Quality Control monitoring, and tests to verify the on-going performance of the mammographic X-ray system, the test equipment listed in Table 3 is required. If a facility elects instead to only perform daily Quality Control testing and some of the tests to verify the on-going performance of the mammographic X-ray system, the equipment listed in Table 4 is recommended. It is, therefore, assumed that the organization or individual which provides the testing service will supply its own test equipment.

Table 3:
Quality Control Equipment (complete set)

Equipment	Accuracy	Reproducibility
Sensitometer	± .02 log exposure units	± .02 log exposure units
Densitometer	± .02 O.D. at 1.0 O.D.	± .01 O.D. at 1.0 O.D.
Dosimeter	± 5%	± 1%
Thermometer	± 0.3°C	± 0.1°C
Non-invasive X-ray tube voltage meter	± 1.5 kVp	± 0.5 kVp
Irradiation time meter	± 5%	± 1%
Light meter	± 10%	± 5%
Phantom, PMMA, 4.2 cm or Breast tissue equivalent material, 4.5 cm	± 0.02 cm	–
Phantom, PMMA, with image quality evaluation objects	–	–
Aluminum filters (> 99.99% purity)	1% thickness	–
Mammographic step wedge	–	–
Compression force test device	± 10%	± 5%
Focal spot test device	–	–
Stopwatch	–	–
Film/screen contact test tool	–	–
Fixer retention test kit	–	–
Magnifying glass	–	–
Ultraviolet light	–	–
Ruler	–	–
Rubber foam for compression plate alignment	–	–
Lead sheets	–	–
Metallic coins	–	–

Table 4:
Quality Control Equipment (basic set)

Equipment	Accuracy	Reproducibility
Sensitometer	± .02 log exposure units	± .02 log exposure units
Densitometer	± .02 O.D. at 1.0 O.D.	± .01 O.D. at 1.0 O.D.
Thermometer	± 0.3°C	± 0.1°C
Phantom, PMMA, 4.2 cm or Breast tissue equivalent material, 4.5 cm	± 0.02 cm	–
Phantom, PMMA, with image quality evaluation objects	–	–
Compression force test device	± 10%	± 5%
Stopwatch	–	–
Film/screen contact test tool	–	–
Fixer retention test kit	–	–
Magnifying glass	–	–
Ultraviolet light	–	–
Ruler	–	–

8.2 Mammographic X-ray system evaluation

During the implementation phase of the Quality Assurance program, the establishment of baseline information and X-ray equipment performance is necessary. After initial evaluation, and at regular intervals during clinical operation, baseline information should be re-evaluated and X-ray equipment performance should be examined. The more technical evaluation should be performed by a medical physicist or individual specialized in mammographic X-ray equipment testing and evaluation.

I. *Mammographic X-ray equipment* – Initially, equipment performance must be fully evaluated. The equipment should be assessed for compliance with the requirements in Section 5.3. Not all the tests need to be repeated on an annual or semi-annual basis since equipment performance for some components is not

likely to change during clinical operation. However, if a component is serviced or replaced, in such a way that performance may be changed, the performance must be re-evaluated. Initial technical evaluation is presented below; Section 8.2.1 presents tests which need to be performed on an annual or semi-annual basis.

X-ray generation

a. X-ray beam filtration and radiation beam quality
b. X-ray tube voltage accuracy and reproducibility
c. Irradiation timer accuracy and reproducibility
d. Reproducibility of radiation output
e. Focal spot size

Beam limiting device

f. Proper radiation beam alignment
g. Light field/X-ray image receptor congruence

Ancillary components

h. Source to image receptor distance indicators accuracy
i. Compression device design and performance
j. Bucky system and grid performance

Other

k. Stability of equipment
l. Mechanical and electrical performance
m. Inspection and replacement of worn or broken components
n. Manufacturer's maintenance schedule

II. *Automatic Exposure Control system* – Initially, Automatic Exposure Control system performance must be fully evaluated for compliance with the requirements in Section 5.3.1, No. 7, for film-screen X-ray mammographic X-ray equipment, or Section 5.3.2, No. 7, for Xeromammographic X-ray equipment and baseline values established. Tests performed during initial evaluation of the system are presented below. Section 8.2.1 presents tests which need to be performed on a semi-annual basis.

a. Reproducibility
b. X-ray tube voltage compensation
c. Minimum response time
d. Thickness compensation response
e. Optical Density setting response
f. Backup timer

III. *Films, screens and cassettes* – For film-screen X-ray mammography, initially, there must be an evaluation of the appropriateness of the film-screen combination being used. This evaluation should be done each time a new type of film or screen is being introduced. Initial evaluation is presented below; Section 8.2.1 presents tests which need to be performed on an annual or semi-annual basis.

a. Adequacy of film-screen combination
b. Film-screen speed uniformity
c. Film-screen contact
d. Screen condition

IV. *Image processing* – The initial evaluation of image processing involves the adequacy of the darkroom environment, and the establishment of baseline values required during Quality Control monitoring. Initial evaluation is presented below.

Darkroom

a. Light tightness
b. Safelight conditions
c. Cleanliness
d. Temperature control of water supply
e. Ventilation system
f. Fixer recovery system

Film Processing

g. Condition of processing equipment
h. Film speed and contrast
i. Level of film base plus fog
j. Solution temperature
k. Replenishment rate
l. Fixer retention analysis
m. Posting of maintenance schedule and Quality Control test results

Xeromammographic processing

n. Condition of processing equipment
o. Selenium plate defects
p. Posting of maintenance schedule and Quality Control test results

V. *Viewboxes* – The evaluation of performance of all viewboxes used for mammograms examination must be done on an annual basis. Initial evaluation is presented below; Section 8.2.1 presents tests performed on an annual basis.
   a. Viewbox surface conditions
   b. Brightness
   c. Light output homogeneity between viewboxes
   d. Light output uniformity
   e. Image masking
   f. Ambient light control

VI. *Imaging characteristics* – The imaging performance of the mammographic X-ray system must be assessed along with the establishment of representative patient dose values. A phantom, with image quality evaluation objects, should be used to test overall performance of the mammographic X-ray system by a quantitative evaluation of the system's ability to image small structures such as fibres, specks and masses, at similar dimensions to those found clinically. The results of phantom image evaluations can therefore be used to establish a baseline value for the Quality Control monitoring program. Another phantom representing compressed breast tissue should be used to measure breast surface dose to calculate the mean glandular dose. The tests for the initial evaluation are presented below and in Section 8.2.1.
   a. Representative breast surface doses with mean glandular dose calculations
   b. Image spatial resolution
   c. Image contrast
   d. Image quality

8.2.1 Description and frequency of tests

Table 5 presents suggested performance criteria and recom-mended frequency of testing for mammographic X-ray equipment. It must be noted that some facilities may require a different frequency of testing than suggested and that for facilities under provincial jurisdiction, different performance criteria and testing frequency may apply.

Table 5:
Description and frequency of tests

Test	Performance Criteria	Frequency
Mammographic X-ray equipment		
Focal spot size	Section 5.3.1 No. 2 or Section 5.3.2 No. 2	Annually
Beam limiting device	Section 5.3 No. 9	Annually
Compression plate alignment	Section 5.3 No. 11	Annually
Radiation output	Section 5.3.1 No. 6 or Section 5.3.2 No. 6	Semi -annually
X-ray timer	Section 5.3 No. 7	Semi-annually
Backup timer	Section 5.3 No. 7	Semi-annually
X-ray tube voltage	Section 5.3.1 No. 5 or Section 5.3.2 No. 5	Semi-annually
Radiation beam quality	Section 5.3.1 No. 4 or Section 5.3.2 No. 4	Semi-annually
Automatic Exposure Control system		
Optical density setting response	Section 5.3.1 No. 7 or Section 5.3.2 No. 7	Semi-annually
X-ray tube voltage compensation	Section 5.3.1 No. 7 or Section 5.3.2 No. 7	Semi-annually
Thickness compensation response	Section 5.3.1 No. 7 or Section 5.3.2 No. 7	Semi-annually
Films, screens and cassettes		
Screen/film speed uniformity	Section 6.5	Semi-annually
Viewboxes		
Brightness	Section 6.4	Annually
Light output uniformity	Section 6.4	Annually
Light output homogeneity	Section 6.4	Annually
Ambient light control	Section 6.4	Annually
Imaging characteristics		
Representative breast surface dose and mean glandular dose calculations	Appendix II	Annually
Image spatial resolution	Baseline	Annually
Image contrast	Baseline	Annually
Image quality	Baseline	Annually

8.3 Quality Control monitoring

Quality Control procedures to be performed in a Quality Assurance program are presented in the following list. Section 8.3.1 presents the tests with the suggested frequency and performance criteria.

I. *Mammographic X-ray equipment* – Mammographic X-ray equipment should be checked for loose or broken components. Breast compression force should be checked.

II. *Darkroom and image processing operation* – There should be regular inspection of darkroom and processing equipment for cleanliness. Light-tightness and correct safelighting should also be assessed on a regular basis. The accuracy of the processor thermometer used should be checked. A daily inspection of film processing solutions levels, and cleanliness of darkroom should be made.

III. *Film, screen and cassette* – Screens should be checked for cleanliness and damage. Cassettes should be checked for cleanliness, wear, warping, fatigue of foam compression material and closure mechanism, light leaks, and film-screen contact. The cassette holder tunnel should be checked for dust and dirt.

IV. *Viewboxes* – Viewboxes should be checked for cleanliness, viewing area discoloration and improper illumination.

V. *Image characteristics* – Test images are needed to monitor the performance of the mammographic X-ray system and image processing. A phantom representing breast thickness should be routinely used to monitor and maintain image density. Another phantom, with image quality evaluation objects, should also be used to test imaging performance of the mammographic X-ray system. The image Quality Control monitoring tests and evaluations must be performed on a regular basis.

VI. *Retake record* – A record of every retake should be made, including the reason for the retake along with any corrective actions. If images contains some patient diagnostic information, they should be maintained in the patient file. Any trends or repeated errors should be identified and corrected.

8.3.1 Description and frequency of tests

Table 6 presents suggested performance criteria and recom-mended frequency of testing for mammographic Quality Control. It must be noted that some facilities may require a different frequency of testing than suggested and that for facilities under provincial jurisdiction, different performance criteria and testing frequency may apply.

Table 6:
Description and frequency of tests

Test	Performance Criteria	Frequency
Mammographic X-ray equipment		
Breast compression device force	Section 5.3 No. 11	Semi-annually
X-ray equipment conditions	Visual acceptance	Monthly
Darkroom and image processing operation		
Level of film base plus fog	Section 6.3	Semi-annually
Safelight test for darkroom fog	Section 6.2	Semi-annually
Fixer retention in film	Baseline	Quarterly
Thermometer accuracy	Section 6.1	Monthly
Darkroom conditions	Visual acceptance	Daily
Replenishment rate	Baseline	Daily
Film processing solution levels	Baseline	Daily
Film processing solution temperature	Baseline	Daily
Sensitometric strip processing	Baseline	Daily
Films, screens and cassettes		
Screen/film contact	Section 6.5	Semi-annually
Screen conditions	Section 6.5	Weekly
Viewboxes		
Viewboxes conditions	Visual acceptance	Weekly
Image characteristics		
Image contrast	Baseline	Weekly
Image quality	Baseline	Weekly
Image density	Baseline	Daily
Retake record		
Retake analysis	Baseline	Monthly

9. Procedures for minimizing dose to personnel

The guidelines and procedures outlined in this Section are primarily directed toward occupational radiation protection. Adherence to these will also, in many instances, provide protection to visitors and other individuals in the vicinity of a facility. The recommendations for safe work practices and procedures should be regarded as a minimum, to be augmented with additional requirements when warranted, to cover special circumstances in particular facilities.

To achieve optimum safety, radiology technologists must make every reasonable effort to keep irradiation of themselves and other personnel as far as practicable below the limits specified in Appendix I.

9.1 General recommendations

1. A room where mammographic X-ray examinations are done must not be used for more than one radiological investigation simultaneously.
2. Except for those persons whose presence is essential for the investigation, all other persons must leave the room when a mammographic X-ray examination is carried out.
3. Personnel must, at all times, keep as far away from the radiation beam as practicable. Radiation exposure of personnel by the primary X-ray beam must never be allowed unless the beam is adequately attenuated by protective screens or protective clothing. Deliberate irradiation of an individual for training purposes or equipment evaluation must never occur.
4. All personnel must take full advantage of available protective devices.
5. Operation of the X-ray tube shall be controlled from the control panel located behind a protective screen or inside a control booth. The technologist must be shielded when exposures are made.

6. If a patient escort or other person is called upon to assist, this person must be provided with protective clothing and be positioned so as to avoid the primary X-ray beam. No one must regularly perform these duties.
7. All technologists operating X-ray equipment and who are likely to receive a radiation dose in excess of 5 percent of the recommended dose limits for radiation workers specified in Appendix I, must wear personnel dosimeters.
8. All entrance doors to a mammographic X-ray room, including patient dressing room doors, must be kept closed while a patient is in the X-ray room. There should be a light or a sign on the outside of the patient dressing room indicating occupancy.
9. Powered-on mammographic X-ray equipment must not be left unattended.
10. Where radiation doses in excess of 5 percent of the recommended effective dose limits for radiation workers specified in Appendix I are regularly received by any one person, appropriate remedial steps must be taken to improve techniques and protective measures.
11. Mammographic X-ray equipment must be operated only by individuals who are properly trained for the equipment and the procedures being performed.
12. Technologists must have a clear view of the patient during every mammographic X-ray examination and must be able to communicate with the patient and/or attendants.

10. Procedures for minimizing dose to patients

The largest single contributor of man-made radiation exposure to the population is dental and medical diagnostic radiology. In total, such use of X-radiation accounts for more than 60 percent of the total man-made radiation dose to the general population.

The risk to the individual patient from a single radiographic examination is very low. However, the risk to a population is increased by increasing the frequency of radiographic examinations and by increasing the number of persons undergoing such examinations. For this reason, every effort should be made to reduce the number of radiographs and the number of persons examined radiographically, as well as to reduce the dose involved in a particular examination. In the case of mammographic screening programs, the benefit from the program must outweigh the risk from an increase of radiation dose to the group being targeted by the program.

To accomplish this reduction, it is essential that patients be subjected to only necessary radiological examinations and, when a radiological examination is required, it is essential that patients be protected from excessive irradiation during the examination.

The recommendations and procedures for the protection of the patient, outlined in this Section, are directed toward the physician, the radiologist and the technologist. They are intended to provide guidelines for elimination of unnecessary radiological examinations and for minimizing doses to patients when radiological examinations are indicated.

10.1 Guidelines for the prescription of diagnostic mammography

The medical practitioner is in a unique position to reduce unnecessary radiation dose to the patient by eliminating examinations which are not clinically justified. The practitioner can achieve this by adhering, as much as possible, to certain basic recommendations. These recommendations are presented below.

1. The request for a mammographic X-ray examination of a patient should be based on a clinical evaluation of the patient and should be for the purpose of obtaining diagnostic information.
2. It should be determined whether there have been any previous mammographic X-ray examinations which would make further examination unnecessary or allow for an abbreviated examination. The previous mammograms should be examined along with a clinical evaluation of the patient.
3. When a patient is transferred from one physician or hospital to another, any relevant mammograms or reports must accompany the patient and should be reviewed by the consulting practitioner.
4. When prescribing a mammographic X-ray examination, the physician should specify precisely the clinical indications and information required.
5. The number of mammographic views required in an examination must be kept to the minimum practicable, consistent with the clinical objectives of the examination.
6. In prescribing mammographic X-ray examinations of pregnant or possibly pregnant women, full consideration must be taken of the consequences of foetal irradiation. While it is generally accepted that the radiation dose to the ovaries and the foetus is low in mammography, the radiation beam should not irradiate the abdominal area.
7. In prescribing mammographic X-ray examinations of patients having breast implants, it should be noted that there may be a need for the use of special compression, positioning and loading techniques, and that the personnel of mammographic X-ray facility should be proficient in performing such procedure.
8. Repeat mammographic X-ray examinations should not be prescribed only because a mammogram may not be of the "best" diagnostic quality if the mammogram contains the required diagnostic information.
9. The quality of mammograms must be monitored routinely, through a Quality Assurance program, to ensure that they satisfy diagnostic requirements with minimal patient dose.
10. A patient's clinical records must include details of all mammographic X-ray examinations carried out.

10.2 Guidelines for screening mammography

In breast cancer screening programs, asymptomatic women undergo mammographic X-ray examinations with the goal to reduce breast cancer death by detecting cancer tumours at an early stage. In such programs, it is important to minimize participant exposure to radiation consistent with obtaining images of optimal diagnostic quality. Therefore, a mammography screening program should not be established unless mean glandular doses are within accepted limits and that a Quality Assurance program is implemented.

1. Selection of population groups for mammographic screening should be based on the concept that the benefit from the program should outweigh any risks from an increase of radiation dose to the group being targeted by the program.
2. Mammographic screening should not be done on pregnant or possibly pregnant women because of the consequences of foetal irradiation. The mammographic X-ray examination should be re-scheduled at a subsequent date.
3. Participants having breast implants should follow the same mammographic screening schedule as recommended for women without implants. However, for these participants, there may be a need for the use of special compression, positioning and loading techniques, and the personnel of mammographic X-ray facility should be proficient in performing such procedures.
4. The number of mammographic views required in an examination must be kept to the minimum practicable, consistent with screening program objectives.
5. Repeat mammographic X-ray examinations should not be prescribed only because a mammogram may not be of the "best" diagnostic quality if the mammogram contains the required diagnostic information.
6. The quality of mammograms must be monitored routinely, through a Quality Assurance program, to ensure that they satisfy diagnostic requirements with minimal patient dose.
7. For mobile mammography screening clinics, it is recommended that image processing be performed on site so that technologists can review their films which will reduce participant callbacks. However, since it is often difficult to stabilize film processors in mobile mammography screening clinics, additional care must be taken to ensure that image processing is optimized. In the situation where image processing cannot be optimized, batch processing at another location is acceptable.

8. Previous mammograms, including baseline mammograms, from screening mammography programs should be available to the radiologist for examination.

10.3 Guidelines for the carrying out of mammographic X-ray examinations

Next to elimination of unnecessary X-ray examinations, the most significant factor in reducing dose is ensuring that an examination is performed with good methodology and proper X-ray tube loading. It is possible, for example, to obtain a series of diagnostically acceptable mammograms and have the organ dose vary widely due to the choice of loading factors. It is the responsibility of the technologist, the medical physicist and the radiologist to be aware of this and to know how to carry out a mammographic X-ray examination with the lowest possible radiation exposure to the patient or breast screening participant.

The recommendations that follow are intended to provide guidance to the technologist, the medical physicist and radiologist in exercising their responsibility towards reduction of patient dose.

1. The mammographic X-ray system must be designed specifically for mammography and the image receptor must be compatible with the system.
2. A film-screen combination that provides good quality diagnostic results must be used. Direct exposure film must never be used in mammography.
3. Except in the case of mammography performed within a screening program, the technologist must not perform any examination which has not been prescribed by a physician responsible for the patient.
4. The dose to the patient must be kept to the lowest practicable value consistent with clinical objectives, and without loss of essential diagnostic information. To achieve this, techniques appropriate to the equipment available should be used and evaluated from time to time in terms of effectiveness.
5. Particular care in patient X-ray protection must be taken when mammographic X-ray examinations of pregnant or possibly pregnant women are carried out, even though the radiation dose to the abdomen and fetus are negligible during normal mammographic X-ray examinations.

6. There may be a need to use special procedures when performing mammographic X-ray examinations of patients with breast implants such as extra views, modified positioning, compression and loading techniques. Particular care of compression techniques must be taken since excessive compression of the implants during mammographic X-ray examination may cause rupture of the implant.
7. In mammography, it is recommended that the field normally be the full size of the image receptor, but not larger than the image receptor support, except at the chest wall. The amount of unexposed areas on the films should be minimal so to avoid the need for masking. Collimated-down views are useful in some purposes, but should be considered as a special procedure.
8. Appropriate compression must be used in all mammographic procedures.
9. Adequate X-ray beam filtration must be used in all mammographic procedures.
10. The technologist should use the maximum focal spot to skin distance consistent with good radiographic loading. For mammographic procedures, distances of less than 50 cm should not be used. For mammographic procedures including magnification, distances of less than 25 cm to the entrance surface of the breast shall not be used.
11. Full details of the mammographic procedures, including retakes, carried out should be noted on the patient's clinical records.
12. Irradiation times should be minimized to avoid unnecessary dose increase from reciprocity law failure and to avoid motion artifacts. This can be accomplished by the use of sufficiently high tube current values.
13. Cassettes should be loaded at least 30 minutes in advance to allow air to escape, and thus improving film/screen contact.
14. The technologist should examine the images after processing in order to verify that the techniques being used are producing diagnostic quality images and that the X-ray equipment is functioning correctly.
15. An appropriate Quality Assurance program must be implemented on mammographic X-ray equipment and on film and Xerographic processing systems.

16. While recommended dose limits have been defined for radiation workers and the general population, there is no specific permissible level recommended for patients undergoing diagnostic X-rays procedures. However, it is possible to provide limits on the amount of radiation breast tissues receive by setting dose limits on the level of radiation a representative breast phantom would receives for a given irradiation. These dose limits are presented in Appendix II.

    For patients the risk involved with exposure to radiation must always be weighed against the medical requirement for accurate diagnosis. However, the dose to the patient should be kept as low as reasonably achievable.

Appendix I

Recommended Dose Limits of Ionizing Radiation

For the purpose of radiation protection, individuals may be classified in one of two categories: those exposed to radiation from man-made sources during their work (radiation workers), and others. The recommended dose limits are given for both categories in the following table. These dose limits are based on the latest recommendations of the International Commission on Radiological Protection (ICRP) as specified in ICRP Publication 60.

It must be noted that the dose limits for radiation workers apply only to irradiation resulting directly from their occupation and do not include radiation exposure from other sources, such as medical diagnosis and background radiation.

Table 7:
Annual Recommended Dose Limits

Applicable Body Organ or Tissue	Radiation Workers	Others
Whole body	20 mSv	1 mSv
Lens of the eye	150 mSv	15 mSv
Skin	500 mSv	50 mSv
Hands	500 mSv	50 mSv
All other organs	500 mSv	50 mSv

1. It is emphasized that any irradiation may involve some degree of risk and the levels suggested in this Appendix are maximum recommended values. All doses should be kept as low as reasonably achievable and any unnecessary radiation exposure must be avoided.
2. ICRP does not recommend discrimination in the dose limits between men and women of reproductive capacity, if the dose is received at an approximately regular rate.

3. For occupationally exposed women, once pregnancy has been declared, the foetus should be protected from external exposure to radiation by applying an equivalent dose limit of 2 mSv to the surface of the women's abdomen for the remainder of the pregnancy.
4. For technologists-in-training and students, the recommended dose limits for members of the public should apply.
5. ICRP does not recommend different limits for individual organs. For occupationally exposed workers, ICRP believes that deterministic effects will be prevented by applying an equivalent dose limit of 500 mSv in a year to all tissues except the lens of the eye, for which it recommends a limit of 150 mSv in a year.
6. For the skin, the equivalent dose is averaged over its whole area. In situations where deterministic effects are possible, the recommended equivalent dose limit for the skin is 500 mSv and is averaged over areas of no more than 1 cm^2. This limit applies to the skin of the face and the hands.
7. ICRP limits allow, in special circumstances, a higher value of dose than is allowed in a one year period, as long as the average dose over a five year period is not greater than the annual limit. This higher value is 50 mSv for occupationally exposed personnel. However, in mammography, there is no circumstance where such provision should apply.
8. Some provincial jurisdictions may have recommended dose limits for some workers, which differ from those listed in this Appendix. Consultation with the proper agency may be required to determine the recommended dose limits in effect in a particular jurisdiction.

Appendix II

Recommended Glandular Dose Limits per Irradiation

While recommended dose limits have been defined for radiation workers and members of the public, there is no specific permissible level recommended for patients undergoing diagnostic X-rays procedures. However, it is possible to recommend limits on the amount of radiation breast tissues receive by setting dose limits on the level of radiation a representative breast phantom would receives for a given irradiation. This breast phantom represents a breast which is composed of 50 percent fat and 50 percent glandular tissues and is compressed to 45 mm thickness. The dose received by the phantom would become a representative mean glandular dose for a breast of similar composition and thickness when compressed.

A mammographic X-ray system producing phantom dose estimates greater than the values set in Table 8 would use more radiation than necessary to produce quality mammographic images and the performance of the mammographic X-ray system and film processing would need to be reassessed.

These glandular dose estimates are calculated by measuring the phantom surface dose while the mammographic X-ray equipment is operated in a normal fashion. The surface dose values are then applied to Table 9 to obtain the mean glandular dose.

Table 8:
Recommended dose limits per irradiation

Procedure	Mean Glandular Dose Limits
Film-Screen Mammography (no grid)	1.0 mGy (100 mrad)
Film-Screen Mammography (grid technique)	2.0 mGy (200 mrad)
Xeromammography	4.0 mGy (400 mrad)

Table 9:
Mean Glandular Dose in mrad (or in mGy) for Surface Exposure of 1 R (or 1 Gy)[1]

	Mo Target / Mo Filter X-ray Tube Voltage (kVp)											W Target Al Filter Combi-
HVL	23	24	25	26	27	28	29	30	31	32	33	nation
0.23	109											
0.24	113	116										
0.25	117	120	122									
0.26	121	124	126	128								
0.27	126	128	130	132	134							
0.28	130	132	134	136	138	139						
0.29	135	137	139	141	142	143	144					
0.30	139	141	143	145	146	147	148	149				170
0.31	144	146	147	149	150	151	152	153	154			175
0.32	148	150	151	153	154	155	156	158	159	160	160	180
0.33	153	154	155	157	158	159	160	162	163	164	164	185
0.34	157	159	160	161	162	163	164	166	167	168	168	190
0.35		163	164	166	167	168	169	170	171	172	172	194
0.36			168	170	171	172	173	174	175	176	176	199
0.37				174	175	176	177	178	178	179	180	204
0.38					179	180	181	182	182	183	184	208
0.39						184	185	186	186	187	188	213
0.40							189	190	191	192	192	217
0.41								194	195	196	196	221
0.42										200	200	225
0.43											204	230
0.44												234
0.45												238

1. Wu X, "Breast Dosimetry in Screen-film Mammography." published in "Screen film mammography; imaging considerations and medical physics responsibilities." Madison, WI, Medical Physics Publishing: 159-175 (1991). Stanton *et al.* "Dosage evaluation in mammography." Radiology 150:577-584 (1984).

Appendix III

Shielding Guides for Storage of Mammographic Film

The following table provides the thicknesses of lead required to reduce the radiation level to the film and loaded cassettes to 1.75 µGy (0.2 mR) for a weekly workload of 1000 mA-min at 35 kilovolts (peak).

Table 10:
Shielding Guides for Storage of Mammographic Film – Storage time for secondary barriers

	Distance from X-ray tube to stored films				
	1 m	2 m	3 m	4 m	5 m
1 day	0.4 mm	0.3 mm	0.2 mm	0.2 mm	0.1 mm
1 week	0.5 mm	0.4 mm	0.4 mm	0.3 mm	0.3 mm
1 month	0.6 mm	0.5 mm	0.4 mm	0.4 mm	0.4 mm
1 year	0.7 mm	0.6 mm	0.6 mm	0.6 mm	0.5 mm

Appendix IV

Provincial/Territorial Radiation Safety Agencies Responsible for Mammographic Facilities

Alberta
Radiation Health Section
Occupational Health Branch
Division of Policy and Professional Services
Government of Alberta
10709 Jasper Avenue
Edmonton, Alberta
T5J 3N3

British Columbia
Radiation Protection Service
Ministry of Health
Government of British Colombia
210 – 4940 Canada Way
Burnaby, British Columbia
V5G 4K6

Manitoba
Radiation Protection Section
Manitoba Cancer Treatment and Research Foundation
100 Olivia Street
Winnipeg, Manitoba
R3E 0V9

New Brunswick
Radiation Protection Services
Department of Health and Community Services
Government of New Brunswick
P.O. Box 5100
Fredericton, New Brunswick
E3B 5G8

Newfoundland
Medical and Hygiene Services
Employment and Labour Relations
Government of Newfoundland
Fall River Plaza, P.O. Box 8700
270 Torbay Road
St. John's, Newfoundland
A1C 4J6

Northwest Territories
Occupational Health and Safety Division
Government of the Northwest Territories
Box 1320
Yellowknife, Northwest Territories
X1A 2L9

Nova Scotia
Department of Health and Fitness
P.O. Box 488
Halifax, Nova Scotia
B3J 2R8

Ontario
X-ray Inspection Service
Ontario Ministry of Health
7 Overlea Boulevard, 6th Floor
Toronto, Ontario
M4H 1A8

Prince Edward Island
Division of Environmental Health
Department of Health and Social Services
Government of Prince Edward Island
P.O. Box 2000
Charlottetown, Prince Edward Island
C1A 7N8

Québec
Responsable de la radioprotection
Direction générale Santé Publique
Ministère de la santé et services sociaux
1075, chemin Sainte-Foy, 16e étage
Sainte-Foy (Québec)
G1S 2M1

Responsable de la radioprotection
Laboratoire de santé publique du Québec
20045, chemin Sainte-Marie
Sainte-Anne de Bellevue (Québec)
H9X 3R5

Saskatchewan
Radiation Safety Unit
Department of Human Resources,
Labour and Employment
Government of Saskatchewan
1870 Albert Place
Regina, Saskatchewan
S4P 3V7

Yukon Territory
Occupational Health and Safety
Government of the Yukon Territory
P.O. Box 2703
Whitehorse, Yukon Territory
Y1A 2C6

Appendix V

Radiation Measurement Units – International (SI) System

Irradiation

The unit of COULOMB/KILOGRAM (C/kg) has not found acceptance as the replacement of the ROENTGEN (R) as a unit of irradiation. Following the lead of the International Electrotechnical Commission, the AIR KERMA (in GRAYS) replaces the EXPOSURE (in ROENTGENS) as the measure of irradiation. The relationship between the two units is as follows:

1 Gy	~	115 R	1 R	~	8.73 mGy
1 mGy	~	115 mR	1 mR	~	8.73 μGy

Absorbed Dose

The GRAY (Gy) replaces the RAD (rad) as the unit of absorbed dose. The relationship between the two units is as follows:

1 Gy	=	100 rad	1 rad	=	10 mGy
1 mGy	=	100 mrad	1 mrad	=	10 μGy

Equivalent Dose

The SIEVERT (Sv) replaces the REM (rem) as the unit of equivalent dose. The relationship between the two units is as follows:

1 Sv	=	100 rem	1 rem	=	10 mSv
1 mSv	=	100 mrem	1 mrem	=	10 μSv

Note: m = milli = 10^{-3}; μ = micro = 10^{-6}

Appendix VI

Glossary of Terminology

The terminology used in this document is based on the International Electrotechnical Commission (IEC), Publication 788 titled: "Medical Radiology, Terminology" and published in 1984. The use of this terminology will allow a greater standardisation between present and future Safety Codes, national and international publications, and the Radiation Emitting Devices Act and Regulations. However, some of the new terms may not be familiar to the reader and are introduced in the present appendix.

Table 11:
Terminology

Terms in this Safety Code	Commonly Used Terms
Beam Limiting device	Collimator
Focal spot	Focus
Irradiation switch	Exposure switch
Irradiation time	Exposure time (to radiation)
Irradiation	Exposure (of an object)
Loading factors	Technique factor
Loading time	Exposure time (to electrical supply)
Loading	Exposure (of an X-ray tube)
Orientation factor	Use factor
Surface dose	Entrance dose

Appendix VII

Radiation Emitting Devices Regulations for Diagnostic X-ray Equipment

Item 12 of Schedule I to the *Radiation Emitting Devices Regulations* establishes standards of design, construction and functioning for diagnostic X-ray equipment such as

> "12. Diagnostic X-ray equipment being X-ray machines designed primarily for the examination of humans but excluding dental X-ray equipment, photofluorographic chest X-ray equipment, radiation therapy simulators and computer assisted tomographic equipment."

The specific portions related to mammographic X-ray equipment within the requirements for Diagnostic X-ray Equipment of the Regulations, at the time of printing of the Safety Code, are reproduced below.

Part XII
Diagnostic X-ray Equipment

Interpretation

1. In this Part,

"aluminium equivalent" in respect of a material under specified conditions, means the thickness of aluminium (Aluminum Association type 1100 alloy) that, under those conditions, affords the same attenuation as that material; (*équivalence en aluminium*)

"attenuation" means a decrease in radiation intensity caused by absorption and scattering in a medium; (*atténuation*)

"automatic exposure control" means a device that automatically controls one or more technique factors to obtain a required amount of radiation; (*contrôle d'exposition automatique*)

"beam limiting device" means a device that restricts the dimensions of the useful beam; (*dispositif de limitation du faisceau*)

"coefficient of variation" means the ratio of the standard deviation to the mean value of a series of measurements, calculated by using the following equation:

$$C = \frac{S}{\bar{X}} = \frac{1}{\bar{X}} \left[\sum_{i=1}^{n} \frac{(X_i - \bar{X})^2}{(n-1)} \right]^{1/2}$$

where x_i = i^{th} measurement
$\bar{x}$ = mean value of the measurements
S = estimated standard deviation
n = number of measurements
C = the coefficient of variation; (*coefficient de variation*)

"control panel" means those parts of the X-ray control having switches knobs, push buttons or other controls necessary for manually setting the technique factors; (*tableau de commande*)

"field emission equipment" means equipment that has an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field; (*équipement d'émission par effet de champ*)

"filter" means material placed in the useful beam to preferentially attenuate certain parts of the X-ray spectrum; (*filtre*)

"half-value layer" or "HVL" means the thickness of specified material that attenuates the beam of radiation to such an extent that the exposure rate is reduced to one-half of its original value; *(couche de demi-atténuation or CDA)*

"image receptor" means a device that converts incident X-radiation into a visible image or into a form that can be made into a visible image by further transformation; (*récepteur d'image*)

"lead equivalent" in respect of a material under specified conditions, means the thickness of lead that, under those conditions, affords the same attenuation as that material; (*équivalence en plomb*)

"leakage radiation" means any radiation,

(a) other than the useful beam, coming from within the tube housing assembly while the exposure switch or timer is activated, or

(b) produced when the exposure switch or timer is not activated; (*rayonnement de fuite*)

"light field" means the area of light in the plane of the image receptor that is directly outlined by the beam limiting device, the

perimeter of which is the locus of points at which the illumination is one-fourth of the maximum in the plane of the image receptor; (*champ lumineux*)

"mobile equipment" means transportable equipment designed to be moved from one location to another, between periods of use, on its own wheels or similar means of support; (*équipement mobile*)

"stationary equipment" means equipment that is permanently installed in one location; (*équipement stationaire*)

"technique factors" means the conditions of operation of the diagnostic X-ray equipment and includes the peak tube potential in kilovolts, the tube current in milliamperes, the exposure time in seconds, the exposure in milliroentgen or combinations of those measurements; (*paramètres d'exposition*)

"tube housing assembly" means the X-ray tube housing with the X-ray tube installed; (*système radiogène*)

"useful beam" means the X-radiation passing through the tube housing port and the aperture of the beam limiting device when the exposure switch or timer is activated; (*faisceau utile*)

"X-ray field" means the area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, the perimeter of which is the locus of points at which the exposure rate is one fourth of the maximum in the intersection. (*champ des rayons X*)

Standards of Design and Construction

General Requirements

2. Every diagnostic X-ray machine shall be designed and constructed in such a manner that when installed and maintained in accordance with the instructions referred to in paragraph 3(a), it functions in accordance with section 19 for as long as the device has its original components or has replacement components recommended by the manufacturer.
3. Every diagnostic X-ray machine shall be equipped with
   (a) installation and maintenance instructions supplied by the manufacturer of the device that, if followed by trained and experienced persons, will enable the device to comply with the requirements of these Regulations; and
   (b) the following written information from the manufacturer with respect to the device:

(i) the maximum power requirements or maximum line current;

(ii) the nominal focal spot size of the X-ray tube target and the method of its determination;

(iii) adequate instructions for assembly and installation, including specification as to adequate line voltage and line impedance; and

(iv) where the device is battery powered, the minimum state of charge necessary for operation.

4. Every diagnostic X-ray machine shall bear

(a) on the external surface of the main X-ray control panel

(i) a warning sign that

(A) includes a statement prohibiting unauthorized use, and

(B) indicates that hazardous radiation emission is produced when the device is in operation,

(ii) the X-radiation warning sign described in section 20, and

(iii) a readily discernible and clearly visible permanent mark or label that sets out with respect to the X-ray control and X-ray generator combination

(A) the name of the manufacturer,

(B) the model designation,

(C) the serial number,

(D) the date of manufacture, and

(E) the country of manufacture;

(b) on the external surface of the X-ray tube housing, a readily discernible and clearly visible permanent mark or label that sets out

(i) with respect to the X-ray tube,

(A) the name of the manufacturer,

(B) the model designation,

(C) the serial number,

(D) the date of installation of the tube in the housing, and

(E) the country of manufacture, and

(ii) with respect to the X-ray tube housing assembly, the minimum permanent filtration in the useful beam provided by the assembly, expressed as millimetres of aluminium equivalent at a specified peak tube potential;

(c) on the external surface of the X-ray tube housing

(i) a permanent mark or marks that define or indicate to within ± 4 millimetres

(A) the location of the focal spot, in the case of single focus X-ray tubes, and

(B) the location of the point midway between the centres of the two focal spots, in the case of double focus X-ray tubes, and

(ii) permanent marks or labels that indicate clearly the anode and cathode terminals; and

(d) on the external surface of any beam limiting device that adds filtration to the useful beam, a permanent mark or label that sets out, with respect to the beam limiting device, the total permanent filtration, expressed in millimetres of aluminium equivalence at a specified peak tube potential.

5. (1) Every diagnostic X-ray machine shall be designed and constructed in such a manner that

(a) all marks, labels and signs required by these Regulations are securely fixed to the device and clearly visible;

(b) all controls, meters, lights or other indicators required by these Regulations are readily discernible and clearly labelled or marked as to function;

(c) the X-ray tube is securely fixed and correctly aligned within the tube housing;

(d) the X-ray tube housing maintains its required exposure position or movement without excessive drift or vibration during operation; and

(e) where more than one X-ray tube is controlled by one control panel, except in the case of a diagnostic X-ray machine specifically designed for two-tube techniques,

(i) it shall not be possible to energize more than one X-ray tube at the same time; and

(ii) there shall be

(A) on or near each tube housing, so as to be clearly visible to the operator, a visible indication when that X-ray tube is connected and ready to be energized, and

(B) at the control panel, a visible indication of which X-ray tube is connected and ready to be energized.

(2) Every diagnostic X-ray machine shall be designed and constructed to include

(a) means to compensate for variations in X-ray tube potential caused by line voltage fluctuations, such that the device complies with the standard of functioning prescribed by subparagraph 19(b)(ii);

(b) either

(i) a visible or audible indicator that warns the operator; or

(ii) a device that prevents X-rays from being produced, when the variation in line voltage exceeds the limits prescribed by subparagraph 19(b)(ii);

(c) a control panel having the following safety features:

(i) separate warning lights, in clear view of the operator, that respectively indicate

(A) when the control panel is energized and the device is ready to produce X-rays, and

(B) when X-rays are produced;

(ii) where the device has adjustable technique factors, electrical meters or other indicators that enable the following factors, or any combination thereof, to be determined before the irradiation is initiated, that is to say,

(A) operating tube potential, in kilovolts,

(B) tube current, in milliamperes, and

(C) the irradiation time, in seconds;

(iii) where the device has non-adjustable technique factors, permanently affixed marks or labels, or electrical meters or other indicators that enable, at specified target-to-image receptor distances, the following factors, or any combination thereof, to be determined before the irradiation is initiated, that is to say,

(A) operating tube potential, in kilovolts,

(B) tube current, in milliamperes, and

(C) the irradiation time, in seconds; and

(iv) where the device is battery-powered, a visual indicator that shows whether the battery is adequately charged for proper operation;

(d) an exposure switch, timer or other mechanism to initiate and terminate the irradiation;

(e) an audible signal to indicate termination of an irradiation;

(f) radiation filters that

(i) are permanently affixed to the exit port of the X-ray tube housing, or beam limiting device or both; and

(ii) for a given X-ray tube potential, result in a half-value layer of the useful beam that is not less than the values given in or obtained by linear interpolation or extrapolation of the table to this section;

(g) keyed filter interlock switches or other positive means to ensure that necessary added filtration is in place in any tube housing assembly that

(i) has permanent inherent filtration of 0.5 millimetre or less aluminium equivalence; and

(ii) is designed to be operated with added filtration; and

(h) where the device is designed to move under remote control around or across a patient, provision for an emergency stop switch, the activation of which immediately terminates both the motion of the device and the production of X-rays.

Table

Design operating range (kilovolts peak)	Measured potential (kilovolts Peak)	Half-value Layer (Millimetres of aluminium)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5

6. (1) An exposure switch provided with a diagnostic X-ray machine

(a) shall be designed so that it requires continuous pressure by the operator to produce X-rays

(b) where it is a foot-switch, shall be so constructed that an unintended exposure does not occur if the switch is overturned;

(c) shall be located so that it cannot be conveniently operated outside a shielded area, except in the case of an exposure switch used in conjunction with mobile X-ray equipment, with spot-film devices, in fluoroscopy or in special procedures; and

(d) where it is part of a mobile machine, shall be equipped with a cable at least 3 metres long.

(2) A radiographic timing device provided with a diagnostic X-ray machine shall be designed so that

(a) it terminates an irradiation on completion of any one of the following:
  (i) a preset time interval
  (ii) a preset product of current and time, (mAs), or
  (iii) a preset number of pulses;

(b) it permits the operator to terminate the irradiation at any time;

(c) it automatically resets to its original position or zero at the termination of the irradiation; and

(d) when it is at the zero or OFF position, an irradiation cannot be initiated.

(3) Permanent diaphragms, cones or other beam limiting devices provided with a diagnostic X-ray machine, as permitted by these Regulations, to collimate the useful beam shall afford the same degree of shielding as that required of the tube housing assembly.

Radiographic Machines

7. Every radiographic machine equipped with an automatic exposure control shall

(a) be designed to include, on the control panel, a clear indication as to when the automatic exposure control mode of operation has been selected;

(b) where the X-ray tube operating potential is 50 kilovolts peak or greater, be designed and constructed to have minimum exposure time capability
  (i) in the case of a field emission machine rated for pulsed operation, equal to or less than the time interval equivalent of two pulses, or
  (ii) in the case of all other machines, equal to or less than 1/60 second or the time interval required to deliver 5 milliampere-seconds, whichever is the greater;

(c) be equipped with a means for ensuring that
  (i) where the X-ray tube potential is less than 50 kilovolts peak, the product of the X-ray tube current and the exposure times does not exceed 2,000 milliampere-seconds per exposure, or
  (ii) where the X-ray tube potential is 50 kilovolts peak or more;

(A) the product of the X-ray tube current and the exposure time does not exceed 600 milliampere-seconds, or

(B) the product of the peak X-ray tube potential, current and exposure time does not exceed 60 kilowatt-seconds per exposure;

(d) be equipped with a back-up timer having a maximum setting,

(i) in the case of a tomographic machine of 10.0 seconds and

(ii) in the case of any other machine, 3.0 seconds; and

(e) be designed

(i) to include, on the control panel, a visible light indicator that will warn the operator, and

(ii) to require manual resetting of the machine before another automatically timed exposure can be made, when termination of automatically timed exposure occurs because the limits specified in paragraph (c) or (d) have been reached.

11. (1) Every radiographic X-ray machine designed specifically for mammography shall be designed and constructed to include

(a) an X-ray beam limiting device that limits the size of the useful beam so that, at any target-to-image receptor distance specified for the machine, the X-ray field in the plane of the image receptor

(i) does not exceed the edge of the image receptor next to the chest wall of the patient by more than 2 percent of the target-to-image receptor distance, and

(ii) does not extend beyond any other edge of the image receptor; and

(b) an image receptor supporting device with sufficient shielding to ensure that the device complies with the standard of functioning prescribed by paragraph 19(e).

(2) Where a radiographic X-ray machine designed specifically for mammography is equipped with a removable fixed aperture beam limiting device, the device shall bear on its external surface clearly visible permanent marking stating

(a) the image receptor size; and

(b) the target-to-image receptor distance for which the devices is designed.

12. Every general purpose radiographic X-ray machine equipped with special attachments for mammography shall be designed

and constructed in such a manner that when the attachments are in service, the machine meets the requirements of section 11.

Limits on Material Between Patient and Image Receptor

18. (1) Subject to subsections (2) and (3), the aluminium equivalent of each of the items listed in column I of the table to this section that is used between the patient and the image receptor in any diagnostic X-ray equipment shall not exceed the limits shown therefor in column II of the table, as determined using an X-ray beam having a potential of 100 kilovolts peak and a half-value layer of 2.7 millimetres of aluminium.

(2) The total aluminium equivalent of all the material, other than the screen and its associated mechanical support panel or grids, that is present between the patient and the image receptor shall not exceed 3.5 millimetres.

(3) Commencing one year from the date of the coming into force of these Regulations, the total aluminium equivalent of all the material, other that the screen or grids, that is present between the patient and the image receptor shall not exceed 3.5 millimetres.

Table

Column I Item	Column II Aluminium Equivalence (millimetres)
Front panel(s) of cassette holder (total of all)	1.0
Front panel(s) of film changer (total of all)	1.0
Stationary table top	1.0
Movable table top (including stationary sub-top)	1.5
Cradle	2.0

Standards of Functioning

19. Every diagnostic X-ray machine when fully assembled for use shall function under normal conditions of use in such a manner that

(a) for any given combination of X-ray tube potential (in kilovolts peak), tube current (in milliamperes), exposure

time (in seconds) of not less than 0.1 second, or for selected radiation exposure to the image receptor (in milliroentgens)

(i) the coefficient of variation of any ten consecutive radiation exposure measurements, taken at the same source-to-detector distance within a time period of one hour, is no greater than 0.05, and

(ii) each of the ten radiation exposure measured is within 15 percent of the mean value of the ten measurements, when the line voltage for each measurement is within plus or minus 1 percent of the mean value for all of the measurements;

(b) for any selected setting of the peak X-ray tube potential,

(i) the actual peak kilovoltage corresponds to the selected value to within plus or minus 5 percent of the selected value, and

(ii) for a line variation of plus or minus 7 percent of its nominal value, the peak kilovoltage, prior to initiation of an exposure, is capable of being maintained to within plus or minus 5 percent of the selected value;

(c) the radiographic timer or automatic exposure control

(i) can be set to control irradiations as short as 1/60 second or 5 milliampere-seconds, whichever is greater,

(ii) at each setting is accurate to 1/60 second or 7 percent of that setting, whichever is greater, and

(iii) at each setting complies with the reproducibility requirements of paragraph(a);

(d) for any fixed indicated value of X-ray tube potential (in kilovolts peak) within the range of values of operating tube potential specified for the equipment, the average ratios of exposure (in milliroentgens) to the product of the tube current and exposure time (in milliampere-seconds) obtained at any two consecutive tube current settings do not differ by more than 0.10 times their sum, that is to say,

$$|x_1 - x_2| < 0.1\,(x_1 + x_2)$$

where x_1 and x_2 are the average mR/mAs values obtained at each of two consecutive tube current settings;

(e) the transmission of the primary X-ray beam through the mammographic image receptor support device referred to in paragraph 11(1)(b) results, with the equipment operated

(i) in the mammographic mode,

(ii) at the minimum target-to-image receptor distance for which it is designed, and

(iii) at the maximum rated peak X-ray tube potential and maximum rated tube current-exposure time product for that peak tube potential,

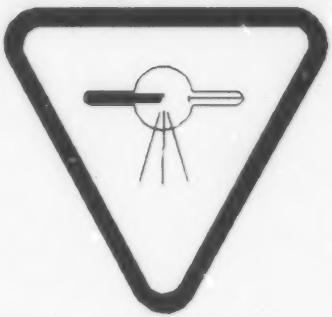
in a radiation exposure averaged over a detection area of 100 square centimetres, with no linear dimension greater than 20 centimetres and centred at 5 centimetres from any accessible surface beyond the plane of the support device that does not exceed 0.1 milliroentgen for each activation of the X-ray tube;

(h) where it is a radiographic X-ray machine designed specifically for mammography, the exposure rate from leakage radiation averaged over a detection area of 100 square centimetres with no linear dimension greater than 20 centimetres, located at 5 centimetres from any point on the external surface of the X-ray tube housing does not exceed 2 milliroentgens per hour;

(i) where there is a possibility of a high voltage appearing across the X-ray tube without the exposure control or timer activated, the emission of X-radiation from the X-ray tube, with the beam limiting device fully open, does not result in an exposure rate, averaged over a detection area of 100 square centimetres with no linear dimension greater than 20 centimetres and centred at 5 centimetres from any accessible external surface of the X-ray tube housing, in excess of 2 milliroentgen per hour;

(j) emission of ionizing radiation by any component other than the X-ray housing assembly, when the X-ray tube is operated at its maximum rated tube potential and current, does not result in an exposure rate averaged over a detection area of 100 square centimetres with no linear dimension greater than 20 centimetres and centred at 5 centimetres from any accessible surface of the component, that exceeds 2 milliroentgens per hour, when averaged over a period of 1 hour.

20. The X-radiation warning sign referred to in section 4 of this Part is a sign that
    (a) is shown in two contrasting colours;
    (b) is clearly visible and identifiable from a distance of 1 metre;
    (c) has no outer dimensions less than 2 centimetres;
    (d) bears the words "**CAUTION X-RAYS**" and "**ATTENTION RAYONS X**"; and
    (e) is designed in accordance with the following diagram:



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